Percutaneous Tibial Nerve Stimulation For the Treatment of Urinary Frequency, Urinary Urgency, and Urge Incontinence: Results from a Community-Based Clinic

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Approximately 16% of the adult population in the United States has symptoms of urinary urgency, urinary frequency, and urge incontinence (Stewart et al., 2003). These symptoms can have a significant impact on quality of life leading to disruptions in work routines and activities of daily living, social isolation, and loss of sleep. Additionally, these symptoms are associated with medical co-morbidities, including skin and urinary tract infections, as well as falls and fractures (Brown, 2002).

However, only 40% of those with symptoms seek treatment (Kinchen et al., 2003). For those seeking treatment, typical first-line therapy encompasses conservative measures, including fluid and food restrictions, bladder retraining, pelvic floor muscle therapy, and the use of protective briefs or pads, possibly in combination with pharmacotherapy. Available medications for the treatment of bladder-related complaints include antimuscarinics, anticholinergics, and occasionally, a tricyclic antidepressant. Antimuscarinic and anticholinergic drugs decrease overactive detrusor contractions by inhibiting the binding of acetylcholine at muscarinic receptors on detrusor smooth muscle cells. Tricyclic antidepressants facilitate urine storage by decreasing bladder contractility and by increasing outlet resistance.

Overactive bladder affects 16% of the adult population. This retrospective analysis evaluated the application of percutaneous tibial nerve stimulation (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.

Key Words: Overactive bladder, urinary frequency, urinary urgency, urge incontinence, percutaneous tibial nerve stimulation, incontinence.

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Urologic Nursing, pp. 177-185.

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Acknowledgment: The author would like to thank Harriet Guthertz, medical writer at Medical Marketing and Communications, St. Paul, MN, for assistance in preparing the manuscript, and Teresa Yurik, MS, The Integra Group, Brooklyn Park, MN, for assistance in performing the statistical analysis.

Despite advances in drug therapy, there is a significant dropout rate for drug therapy. In a study of over 23,000 patients with symptoms of overactive bladder (OAB), approximately 60% of patients had stopped drug therapy within 90 days, and over 80% stopped before one year (Perfetto, Prasan, & Jumadiiova, 2005). Patients may be refractory to medications, or the use of medications may be contraindicated for patients with OAB who have concurrent medical conditions, such as narrow-angle glaucoma, slow gastric emptying, and urinary retention.
Introduction
Urinary urgency, frequency, and urge incontinence are common conditions that can severely impact a patient’s quality of life and also result in medical co-morbidities. Many patients do not achieve optimum symptom management with common first-line treatments, including pelvic floor muscle therapy, bladder retraining, and pharmacotherapy. Percutaneous tibial nerve stimulation (PTNS) is a minimally invasive percutaneous neuromodulation therapy that can be used to treat select patients with symptoms of urinary urgency, urinary frequency, and urge incontinence.

Methods
Fifty-three patients presenting with documented urgency, frequency, and urge incontinence who failed to obtain adequate symptom relief with diet modification, Kegel exercises, biofeedback, or drug therapy were treated with 12, 30-minute PTNS sessions performed approximately one week apart.

Results
The 53 patients included in this retrospective analysis experienced a statistically significant mean decrease in day and night voids and episodes of urge incontinence when compared to baseline. PTNS therapy was particularly effective in reducing or curing incontinence episodes. There were no significant side effects or adverse events.

Conclusion
PTNS was shown to be a safe and effective treatment for symptoms of urinary urgency, urinary frequency, and urge incontinence in this group.

Level of Evidence – VI
(Melnyk & Fineout-Overholt, 2005)

The efficacy of drugs is limited by compliance issues due to intolerable side effects or by patients who do not wish to continue chronic, systemic drug therapy. Neuromodulation in the form of percutaneous tibial nerve stimulation (PTNS) is an attractive option for these patients. PTNS is a minimally invasive, office-based therapy that can meet the needs of patients who want an effective alternative treatment for symptoms of urinary urgency, urinary frequency, and urge incontinence in which a surgical intervention is not indicated or in those who do not wish to pursue a surgical intervention (Govier, Litwiller, Nitti, Kreder, & Rosenblatt, 2001). PTNS therapy provides health care practitioners with an additional tool in the therapeutic armamentarium for OAB. Demonstrated as a safe, effective, and well-tolerated treatment for symptoms of urinary frequency, urinary urgency, and urge incontinence (Govier et al., 2001), PTNS can be delivered in an office-based setting by a trained clinician under a physician’s direction.

Overview of PTNS Therapy
PTNS is a non-drug, non-surgical therapy involving the use of electrical stimulation to modulate bladder function. Stimulation of the posterior tibial nerves for the treatment of urge incontinence was first reported in 1983 (McGuire, Zhang, Horwnski, & Lytton, 1983), and the technology was commercialized in the 1990s. Although the exact mechanism of action is unknown, neuromodulation for urinary dysfunction is based on the premise that nerves in the sacral plexus regulate bladder function and can change bladder activity. The posterior tibial nerve is a mixed sensory and motor nerve containing fibers that originate from L4 to S3 (Cooperberg & Stoll, 2003). During PTNS therapy, impulses from the tibial nerve travel to the sacral nerve plexus, thereby modulating signals to the bladder (see Figure 1). It is important to note that the efficacy of PTNS therapy in patients with diabetic neuropathy is unknown.

The current generation PTNS system, the Urgent® PC Neuromodulation System, UPC-200, (Uroplasty, Inc., Minnetonka, MN) (see Figure 2), has been available since 2006. With the Urgent® PC system, PTNS therapy can be delivered easily and conveniently in an office setting by a midlevel provider or RN under a physician’s direction. To deliver therapy, the patient is placed in a com-

Figure 1.
The posterior tibial nerve is targeted for stimulation during PTNS therapy. From the tibial nerve, the impulse travels to the sacral nerve plexus which regulates bladder and pelvic floor function.
Figure 2. The Urgent PC® system used to administer percutaneous tibial nerve stimulation (PTNS) therapy consists of a hand-held external pulse generator, a lead wire, a needle electrode, and a surface electrode.

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Figure 3. PTNS therapy can be administered in an office setting with the patient seated comfortably. The area near but not directly on the posterior tibial nerve is targeted for stimulation during PTNS therapy. The target can be identified as approximately three fingerbreadths (5 cm) cephalad to the medial malleolus and approximately 1 fingerbreadth (2 cm) posterior to the tibia.

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Figure 4. Maintain a 60-degree angle with the needle electrode while advancing it in a path that is parallel to the tibia.

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Figure 5. A surface electrode is placed near the medial aspect of the calcaneus on the same leg as needle electrode insertion.

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comfortable seated position, and a 34-gauge needle electrode is inserted near but not directly on the tibial nerve (approximately three fingerbreadths [5 cm] cephalad to the medial malleolus and approximately 1 fingerbreadth [2 cm] posterior to the tibia) (see Figure 3). The needle electrode is placed in a position creating a 60-degree angle between the electrode and the ankle, while advancing it in a path that is parallel to the tibial nerve.

When appropriately positioned, approximately 2 cm of the needle electrode will be inserted in the leg (see Figure 4). A custom lead wire is then connected to the Urgent® PC stimulator, and a grounding surface electrode is placed near the medial aspect of the calcaneus on the same leg as the needle insertion (see Figure 5). The lead is connected to the needle electrode using an integrated clip. The stimulator is then used to verify the correct electrode position by slowly increasing the current and observing the patient’s foot for toe flex or fan, extension of the entire foot, or stimulation of the heel and/or foot, as an indicator for successful placement. After proper electrode position has been verified, stimulation is started at the observed level of response if tolerable, or
the current setting is reduced by one increment for patient comfort. Current is adjustable from 0.15 mA to 9 mA. Therapy is then delivered continuously for 30 minutes. PTNS therapy is well tolerated, and has been described as producing a sensation of tapping, tingling, or vibration.

The recommended initial course of PTNS therapy for symptoms of urinary frequency, urinary urgency, and urge incontinence consists of a series of 12 individual treatments, each approximately one week apart. This protocol was described by Govier et al. (2001) and was used as the basis for United States Food and Drug Administration (FDA) approval of the therapy. It may also be possible to titrate dosages of OAB drugs downward during the initial course of PTNS therapy. To maintain therapeutic effect after the initial 12 treatments, the interval between follow-up sessions is individualized according to the patient’s response. In this practice, follow-up session frequency has ranged from two weeks to several months. Because the treatment is minimally invasive, completely reversible, and can be stopped at any time, it does not preclude the use of other therapeutic options, including new drugs and/or devices.

No significant product-related adverse events or side effects have been associated with the therapy. However, it should be noted that PTNS therapy is contraindicated in patients who have the following history or conditions (Uroplasty, Inc., 2006):

- Patients with pacemakers or implantable defibrillators.
- Patients prone to excessive bleeding.
- Patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function.
- Patients who are pregnant or planning to become pregnant while using this product.

Additionally, the product is not intended for intracardiac or transthoracic use. Concurrent use of medical monitoring equipment during stimulation is not recommended. The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

PTNS therapy is an option for patients with symptoms of urinary frequency, urinary urgency, and urge incontinence who are refractory to drug therapy or who experience intolerable side effects of drug therapy. It also provides a therapy option for patients who do not wish to pursue more invasive procedures, including botulinum toxin type A injections (Botox®), implantable neuromodulation therapy, or surgery.

**Review of the Literature**

According to data on file at Uroplasty, Inc., PTNS therapy has been the subject of approximately 60 papers in the medical literature worldwide. A prospective, multicenter FDA investigational device exemption study utilizing PTNS on patients with symptoms of OAB who had failed medical therapy, Kegel exercise, biofeedback, and pelvic floor stimulators enrolled 53 patients and had a mean follow up of 12 months (Govier et al., 2001). Of the 47 patients who completed the 12-week study, 71% achieved 25% or more reduction in mean daytime voids and/or nighttime voiding frequency. On average, patients noticed a 25% reduction in mean daytime frequency, a 21% reduction in mean nighttime frequency, and a 35% reduction in urine incontinence episodes, with a mean follow up of 12 weeks (Govier et al., 2001).

Another prospective study followed 90 patients with OAB. Of these, 56% achieved 50% or more reduction in the number of leakage episodes per 24 hours (Vandoninck et al., 2003).

One randomized study compared PTNS therapy (12 weekly sessions, 30 minutes each) with tolterodine therapy (2 mg, BID) in 31 women with symptoms of urge and urge incontinence. This study found no statistically significant difference between the two groups in terms of the major endpoints of mic turitions in 24 hours and the patient’s quality of life, and the minor endpoints of incontinence episodes in 24 hours and side effects of the therapy after 12 months of follow up (Preyer et al., 2007). However, the PTNS group experienced a significantly lower rate of side effects – 3.4% in the PTNS group versus 20.7% in the tolterodine group. This led the authors to conclude that PTNS is particularly advantageous given the number of comorbidities and high drug load in their study population.

In a recent prospective, multicenter study, 100 patients (94 female) with OAB at 11 U.S. centers were randomized 1:1 to either 12 weekly treatments of PTNS therapy or tolterodine tartrate extended release 4 mg/day for 12 weeks (a few patients were reduced to 2 mg/day based on tolerability) (Peters et al., 2008). This study was powered to show a non-inferiority margin of 20%. This means that the mean reduction in the number of voids per 24 hours in the PTNS arm of the study was no more than 20% lower than the mean reduction in the number of voids per 24 hours in the tolterodine arm. Based on an analysis of 41 patients in the PTNS group and 43 patients in the tolterodine group, both treatments were well tolerated and resulted in similar improvements in voids per day, voids at night, and urge incontinence as measured by a 2-day voiding diary. Quality-of-life scores showed a statistically significant improvement from baseline for both groups. The comparable efficacy between both treatment groups led the authors to conclude that PTNS may be considered a first-line therapy for OAB.

It is important to note that the relatively small sample sizes in these studies are typical of device studies, which usually have smaller sample sizes than drug studies.
Table 1.
Percutaneous Tibial Nerve Stimulation (PTNS) Protocol Used

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PTNS sessions</td>
<td>12</td>
</tr>
<tr>
<td>Frequency</td>
<td>1 session weekly</td>
</tr>
<tr>
<td>Duration of each session</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Current setting</td>
<td>Titrated from 0.15 mA to 9 mA</td>
</tr>
</tbody>
</table>

Note: Adapted from Govier et al., 2001

Experience at a Community-Based Urology Practice

Purpose

The purpose of this study was to report an initial experience in an independent, community-based, nurse practitioner-led continence practice in an effort to gain further knowledge about this novel therapy. Researchers hope this information may be valuable to other health care practitioners interested in incorporating this therapy into their therapeutic armamentarium for bladder dysfunction. This study involved a retrospective chart review to describe the patient population, the change in baseline symptoms after a course of 12 PTNS therapy sessions, and the place of PTNS in the continuum of care for patients suffering with the chronic condition of overactive bladder syndrome.

Methods

From May 2006 through April 2008, 53 patients (52 female), all Caucasian, with chronic OAB symptoms were referred to a community-based, nurse practitioner-led continence practice. Complete medical, surgical, medication, and social histories were completed for all patients. All physical and genitourinary examinations were performed by the same nurse practitioner specializing in continence management, and each patient completed a 3-day voiding diary. Patients with urgency, frequency, and urge incontinence documented on the 3-day voiding diary, who failed to achieve symptom relief with treatments, such as diet modification, Kegel exercises, biofeedback, or behavioral or medical therapy, were offered PTNS therapy.

All 53 patients received PTNS therapy according to a protocol described by Govier and colleagues (2001) of an initial course of 12 PTNS treatments given approximately once per week that were 30 minutes duration (see Table 1). In the protocol used by Govier et al. (2001), patients were older than 18 years with documented urgency, frequency, and/or pelvic floor dysfunction resulting in a mean frequency of at least 10 voids per day and/or 3 per night (based on a 72-hour pre-intentional evaluation during the screening period). These patients failed more conventional medical therapy. Exclusion criteria included an active urinary tract infection, structural abnormality, or urologically proven instability secondary to a known neurological condition (hyperreflexic neurogenic bladder). These criteria were followed in this patient population; exceptions included those patients who had more than 8 daytime voids, 1 or more night void(s), or any episodes of incontinence. Because 6 to 8 voids per day can be considered normal (Van Haarst, Heldeweg, Newling, & Schlatmann, 2004), more than 8 voids per day was used as a cut off in defining OAB.

The number of daily voids, nighttime voids, and urge incontinence episodes were recorded using voiding diaries at baseline and after 6 and 12 PTNS treatments were completed. If the patient’s urinary symptoms responded to PTNS therapy, a treatment plan was prescribed on an individualized basis for continued patient symptom relief.

Data Analysis

Statistical analysis was conducted on study outcome measures for patients who completed a series of 12, 30-minute PTNS treatments. An independent biostatistician using SAS version 9.1 analyzed the data. A p value less than 0.05 was considered significant.

Findings

One male and 52 female patients completed 12 PTNS sessions. The mean patient age was 68 years (range 37 years to 90 years). Patients reported a variety of voiding dysfunction symptoms (see Table 2), as well as...
morbidities and concomitant conditions (see Table 3). At baseline, 34 of the patients were on at least one OAB medication (see Table 4).

All patients experienced at least one abnormal symptom of an overactive bladder at baseline defined as more than 8 daytime voids (n = 33), 1 or more night voids (n = 50), or any episodes of incontinence (n = 42). Twelve PTNS treatments with the Urgen® PC system resulted in a statistically significant decrease with each of these symptoms from baseline to 12 weeks.

For the 33 patients with an abnormal number of daytime voids, mean daytime voids decreased significantly from an average of 13.8 at baseline to 7.9 after 12 treatments (p < 0.0001) (see Figure 6). Patients experienced a statistically significant average decrease in daytime voids of 27.9% from baseline (p < 0.0001).

Similarly, the mean voids per night decreased from an average of 3.1 at baseline to 1.2 after 12 treatments (p < 0.001) (see Figure 7). Patients experienced an average 63.5% decrease in nighttime voids from baseline (p < 0.0001). A total of 82% (41 of 50) patients with 1 or more night voids at baseline showed some improvement in night voids.

Of importance to patients who report that incontinence is the most distressing and socially limiting aspect of their urinary dysfunction, treatment with PTNS therapy was particularly effective in reducing or curing urge incontinence episodes. A total of 42 patients reported urge incontinence at baseline with an average of 4.9 incontinence episodes daily (see Figure 8). After only 6 PTNS treatments, the average number of incontinence episodes for patients who reported incontinence episodes at baseline decreased dramatically to 1.2 episodes (p < 0.0001), with patients experiencing an average 69.4% decrease to their number of incontinence episodes. After 12 PTNS treatments, the number of incontinence episodes improved further to a total average of 0.7 daily episodes (p < 0.0001). Thirty-seven of the 42 patients reporting incontinence at baseline (88%) improved with 59.5% (25 of 42) patients cured (such as reporting no incontinence episodes during the period of review for the study). A total of 88.1% (37 of 42) patients experienced some improvement to their urge incontinence, with patients reporting a substantial 79.3% average decrease to their incontinence episodes (p < 0.0001).

The efficacy of PTNS therapy in patients concurrently taking OAB medications was also analyzed. Since 31 of the 34 patients on OAB medications were taking only one OAB medication, data were analyzed in terms of whether a patient was taking an OAB medication and receiving PTNS therapy or whether the patient received PTNS therapy alone. This analysis showed that PTNS therapy is highly effective regardless of whether patients are taking OAB medications at baseline (see Figures 9-11). For example, mean daytime voids decreased from an average of 10.6 at baseline to 7.4 after 12 PTNS treatments.
treatments \( p = 0.0007 \) for patients on medication at baseline \( n = 34 \) compared to an average decrease from 12.3 at baseline to 7.8 after 12 PTNS treatments \( p = 0.0004 \) for patients who were not taking OAB medications at baseline \( n = 19 \) (see Figure 9). Similar results were obtained in an analysis of night voids (see Figure 10) and urge incontinence episodes (see Figure 11).

Finally, there were no complications or adverse events with PTNS, and patients were quite pleased with the treatment process and outcomes. They viewed PTNS as a safe and effective way of controlling their bladder symptoms and reported they looked forward to the 30-minute treatment sessions as a time for rest, relaxation, reading, or meditation.

**Discussion**

Developing an effective treatment plan for symptoms of urinary frequency, urinary urgency, and urge incontinence can sometimes involve the trial of several therapy modalities, starting with conservative measures, such as pelvic floor exercises, and behavioral therapies and medications. However, for a significant number of patients, these measures may not result in satisfactory symptom relief. They may experience intolerable side effects from the prescribed medications or have compliance issues, or their symptoms may be refractory to these first-line measures. The question of how to proceed can be challenging. Patients may be unwilling to try additional medications, but at the same time, may not be ready for a surgically implanted device or surgical reconstruction. PTNS therapy is an option for these patients and can be used concomitantly with behavioral therapies and pharmacotherapy. Considering the social embarrassment associated with incontinence, the reduction in urge incontinence seen in this study likely resulted in a significant positive impact on the patient’s quality of life.

In this retrospective review, PTNS was shown to be effective either with or without concurrent OAB medications. There were no significant differences between the groups of patients defined by medication use at baseline in terms of mean change in daytime voids, nighttime voids, and urge incontinence episodes. PTNS therapy was found to reduce or cure incontinence episodes in a majority of patients reporting urge incontinence at baseline for the duration of the study. Frequency and nocturia in patients reporting nighttime voids at baseline were also improved. The therapy is minimally invasive and can be administered by appropriately trained practitioners in an office setting. The therapy has not been associated with any significant side effects or adverse events, and its use does not preclude the use...
of other therapies, including more invasive options in the future. This experience with PTNS therapy confirms previously published results demonstrating a significant reduction in mean voids during the day and night, as well as in a reduction in urge incontinence episodes.

A number of factors are necessary to successfully incorporate the therapy into the continuum of care, including patient selection, patient education, practitioner technique, and documentation. A thorough medical history and physical examination are necessary prior to prescribing PTNS. Every effort should be made to determine if there is a reversible cause of urinary urgency, urinary frequency, and urge incontinence. The pathophysiology of bladder outlet obstruction, bladder inflammation, overactivity, derangement, spinal cord injury, or aging should be considered as the etiology of these symptoms.

Reversible causes of OAB may include constipation, urinary tract infection, atrophic vaginitis, ingestion of irritative food or fluids, or the consequences of chronic disease. All patients in this study were evaluated and assessed with these factors in mind. Bladder diaries are an essential and detailed record of a patient’s response to medications including efficacy and toleration. In case of questions in differentiation of stress and urge incontinence during the diagnostic workup, urodynamic testing may be useful; however, this was not the case for any patients included in this retrospective analysis. Similarly, cystoscopy can be a useful tool for the diagnosis of intractable urgency or assessment of other findings indicating further investigation. Again, this was not performed in the patients discussed in this article.

Prior to prescribing PTNS therapy, the entire treatment regimen should be reviewed with the patient. This includes setting expectations regarding what happens during a PTNS therapy session, the length of a session, the number of weekly sessions required, and the potential need for follow-up sessions. The patient must also realize the need for continued commitment to behavioral treatments and the ongoing titration of medications.

As part of this author’s practice, continued pelvic floor education measures, including Kegel exercises, bladder retraining, and habit training, have been important. Urge reduction measures, including fluid management and the avoidance of bladder irritants, were also continued.

After starting PTNS therapy, a treatment log should be started, and the results should be documented carefully to include a quality-of-life survey and voiding diaries at baseline, and after treatment 6 and 12. The OAB-q, version 1, 2004 survey (Coyne, Matza, & Thompson, 2005) was used to document quality of life in this study. Similarly, a therapy continuance plan should be developed if needed and the results documented. These records prove valuable for use during ongoing patient education and billing.

Limitations

This study was limited by the fact that it was a retrospective analysis. Although both men and women are affected equally by OAB, the overwhelming majority of patients undergoing PTNS therapy in this author’s practice are female. Because descriptive statistics were used to analyze data in addition to the resultant small n sizes, meaningful subgroup analysis that might provide further insight into which patients could benefit most from PTNS therapy was not performed.

Additional limitations included that a standardized tool was not used to capture quality-of-life data and that these results cannot be generalized to the larger population of patients with OAB. The lack of an accepted, standardized protocol for treatment with PTNS also makes the comparison of outcomes among studies using this product difficult.

Implications for Nursing Practice

PTNS is a successful alternative for the treatment of urinary urgency, urinary frequency, and urge incontinence when medications and other behavior interventions do not provide the desired level of bladder control. PTNS therapy can be used independently or in conjunction with medications to achieve normal voiding patterns and reduce urgency. The time allotted for each PTNS therapy session also provides an advanced practice nurse with the opportunity to reinforce behavioral interventions critical for achieving long-term bladder control.

Conclusions

Results of previously published clinical studies and those obtained in the 53 patients treated with PTNS in this retrospective study in an independent community-based, nurse practitioner-led continence practice indicate that PTNS significantly decreased symptoms of urinary frequency and urgency. It was particularly effective in reducing or curing urge incontinence, which is perhaps the most distressing aspect of urinary dysfunction for patients. Patients have been satisfied with the results and pleased with the availability of this treatment alternative. In summary, PTNS therapy can be successfully incorporated into the therapy continuum in a community-based setting.

References


