

Treatment of Urge Incontinence With Combination Neuromodulation Techniques

Earl A. Surwit, MD; Jill Campbell, RN, BSN; Kathy Karaszewski, RN, MBA, HCM

Abstract

Objectives: The hypothesis of this study was that by adding percutaneous tibial nerve stimulation (PTNS, using an Urgent PC device by Uroplasty Inc) to pelvic floor muscle rehabilitation therapy (PFMR, including exercises and the use of an Evadri Bladder Control System by Hollister Inc), we would uncover an additive effect or even a synergy between the treatments, with the combination being more successful than either therapy alone for the treatment of urinary urge incontinence in women.

Material and Methods: Ninety-four female patients with urge-urinary incontinence were treated sequentially (on the same day) with both 30 minutes of PFMR and 30 minutes of PTNS once weekly for 12 weeks at the Southern Arizona Urogynecology Center, Tucson, Arizona. PFMR consisted of pelvic floor muscle training that comprised 3 parts: exercises, biofeedback, and electrical stimulation. For the first 6 weeks, electrical stimulation was to the pudendal nerve (100-Hz neuromodulation) and for the second 6 weeks to the hypogastric nerve (10-Hz neuromodulation). Also as part of the treatment, patients applied either vaginal estrogen cream or pomegranate oil to vaginal tissues 3 times per week to optimize bladder and pelvic floor muscle functions.

The ages of the 94 patients ranged from 38 to 91 years with the median age being 66. The median duration of incontinence was 5 years; mean number of urge-incontinent episodes was 2.5 per day.

The criteria for successful treatment were an absence of incontinence episodes (being dry) at the end of treatment and an overactive bladder's score (OAB)-V8 of less than 8, indicating that the bladder was not overactive. All patients were followed up in the office as long as they lived in Arizona. The median follow-up time was 20 months.

Results: The results in these 94 patients with urge incontinence revealed an 88% success or dry rate at the completion of treatment with an OAB-V8 score of less than 8. The remaining 12% of patients had a mean improvement of 81% in their incontinence episodes. There were no significant side effects.

Conclusions: Results of the addition of PTNS to traditional PFMR therapy, which in this case included neuromodulation of both pudendal and hypogastric nerves, suggest that this novel combination is a highly successful, safe option for treatment of refractory urge incontinence and superior to either treatment alone—by a factor of almost 2 times in our study when compared with other studies.

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Female urinary stress and urge incontinence are extremely common problems in the world, with an incidence of 34% in all women.¹ Stress incontinence is the loss of urine while under physical strain such as from coughing, laughing, sneezing, or exer-

cise; urge incontinence is the loss of urine when there is an urge to urinate and the person does not make it to the bathroom in time.

The negative effects of incontinence on patients' lives are substantial, often engendering a reluctance to travel, shop, dine at a restaurant, go to a movie, or attend religious services; some patients even become completely housebound. Incontinence also has a significant adverse impact on sexual function should leakage occur during intercourse. Vulvar and perineal irritation and rashes are also common side effects. A quality-of-life survey for patients with urinary incontinence showed the same low scores as for patients with severe diabetes, coronary artery disease, or serious depression.²

Unfortunately, only 20% of female patients with urinary incontinence will seek help.¹ In the United States, there are also 33 million women with overactive bladders (OAB), defined as an irrepressible urge to urinate or a need to urinate frequently; only 8% of these women seek help.³ OAB is frequently a precursor to urge incontinence.

The number 1 reason stated for not obtaining medical attention for incontinence is fear of surgery⁴—the standard of care around the world for both stress incontinence and mixed incontinence (stress and urge-urinary incontinence combined) often includes surgery, although it is not recommended for urge incontinence. In the United States, only 23% of women who seek help with incontinence will consent to major surgery.⁵

The intent of this study was to focus on urge incontinence. Medical treatment of urge incontinence across the world generally consists of the use of pharmaceutical agents such as antispasmodics, anticholinergics, and imipramine. Side effects such as dry mouth and constipation from these treatments are frequent. These pharmacologic interventions will improve incontinence for a large number of patients, but only for a short period of time.⁶ In particular, anticholinergic drugs are not curative and are also not tolerated for many patients in the long term. At 6 months, the compliance rate for these anticholinergic drugs is 18% to 30%.⁶ They are, furthermore, potentially dangerous in older patients whose blood-brain barrier has become less effective, allowing more of the drug to penetrate the central nervous system (CNS)⁷ and increasing the likelihood of CNS side effects.

One alternative to drugs is pelvic floor muscle rehabilitation (PFMR) therapy, a pelvic floor muscle training that traditionally consists of 3 parts: exercises, biofeedback, and electrical stimulation. According to published studies, a decrease in incontinent episodes after PFMR occurs in 60% to 80% in the short term for patients with urge incontinence.⁸⁻¹¹ Unfortunately, there is very little long-term follow-up in these studies.¹² The cure (dry) rates for PFMR for urge incontinence ranged from 30.2% to 33% in several studies.⁸⁻¹¹

Biofeedback is accomplished via a patch electrode on the patient's abdomen along with a vaginal probe. There is a specific electromyographical pattern on the computer screen (patient and nurse each have a computer screen; see Figure 1) for the pelvic floor muscles only. Should any ancillary muscle (abdomen,



Figure 1. Evadri Bladder Control System

A machine designed for pelvic floor muscle rehabilitation therapy. Treatments include surface electromyogram (EMG) biofeedback, intracavity EMG biofeedback, electrical stimulation, and pressure manometry.

thigh, or buttocks) be stimulated, the pattern changes and the patient is notified. The nurse asks the patient to squeeze her pelvic floor muscles and lets her know if she uses anything but the pelvic floor muscles.

The electrostimulation piece of PFMR works by stimulating the pelvic floor musculature and the pudendal nerve, which leads to a second contraction of the pelvic musculature. Electrical stimulation of the hypogastric nerve quiets the overactive bladder (ie, the detrusor muscle) through the cholinergic muscarinic network.

Percutaneous tibial nerve neuromodulation¹³ (also called percutaneous tibial nerve stimulation or PTNS) is a new therapy that has been approved by the FDA for urge incontinence and overactive bladder. PTNS quiets or relaxes the bladder (ie, the detrusor muscle) by inhibiting the parasympathetic neurological pathways (voiding) and stimulating the sympathetic neurological pathways (storage).^{13,14} This is accomplished by stimulating the sacral neurological complex of nerves along with the Onuf's nucleus, located at S2-S3. Onuf's nucleus stimulation inhibits the bladder through inhibition of the parasympathetic ganglion and subsequent secretion of both serotonin and norepinephrine, which strengthen the urethra (see Figure 2).

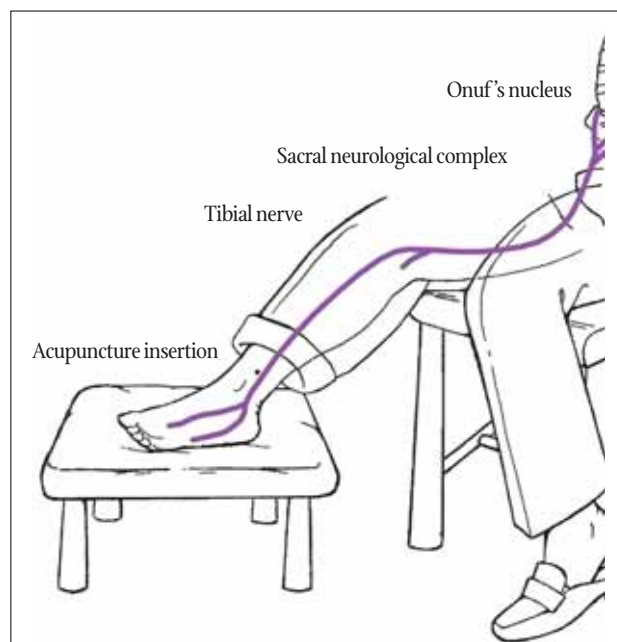


Figure 2. Percutaneous Tibial Nerve Neuromodulation

Percutaneous tibial nerve neuromodulation (also called percutaneous tibial nerve stimulation or PTNS) quiets or relaxes the bladder by inhibiting the parasympathetic neurological pathways (voiding) and stimulating the sympathetic neurological pathways (storage). This is accomplished by stimulating the sacral neurological complex of nerves along with the Onuf's nucleus, located at S2-S3. Onuf's nucleus stimulation inhibits the bladder through inhibition of the parasympathetic ganglion and subsequent secretion of both serotonin and norepinephrine, which strengthen the urethra.

Using the devise shown in Figure 3, a small, slim needle and electrode are inserted near the tibial nerve and connected to a battery-powered stimulator. Impulses then travel the tibial nerve to the sacral plexus.

Although not considered an acupuncture procedure, PTNS does require use of an acupuncture needle, inserted just superior to the medial ankle, to directly stimulate the tibial nerve. An electrode is attached to the needle and a grounding pad to the bottom of the patient's foot (see Figure 3). A neuromodulator then stimulates the tibial nerve, starting at 1 milliamp and increasing to a maximum of 10 milliamps. The current is raised until there is clear evidence of neuromodulation of the tibial nerve: This can produce a sensory response, with intense vibration or tingling in the ankle, foot, or toes, or a motor response, with contraction of the toes (these patients will also have sensation in the toes as well). Some patients actually will feel the current go up the leg.



Figure 3. Percutaneous Tibial Nerve Stimulation (PTNS) Device

Although not considered an acupuncture procedure, PTNS does require use of an acupuncture needle, inserted just superior to the medial ankle, to directly stimulate the tibial nerve. An electrode is attached to the needle and a grounding pad (both shown) to the bottom of the patient's foot.

PFMR mechanisms of action are completely different from those of PTNS. Therefore, we felt there was great potential for an additive effect or even synergy between these 2 different treatment modalities. The intent of this prospective clinical trial was to determine whether adding PTNS to traditional pelvic floor muscle rehabilitation would successfully treat patients with significant urge incontinence better than each therapy alone.

Materials and Methods

This prospective trial included 94 female patients with urinary urge incontinence who met the study enrollment crite-

ria (explained below) and then received treatment at the Southern Arizona Urogynecology Center, Tucson. Primary care physicians, obstetrician gynecologists, urologists, and neurologists referred most of the patients; some sought consultation on their own. Ages ranged from 38 to 91 years, with a median age of 66 years. The duration of incontinence varied from 4 months to greater than 20 years, with a median duration of 5 years. Before treatment, the mean number of spillage accidents per day was 2.5.

A physician completed a history and physical examination on all patients who applied for the study, and each underwent a routine urinalysis. The physician also administered a Urinary Questionnaire to each patient, collecting data on 36 relevant points; 1 question was whether urge urinary-incontinence symptoms significantly interfered with the patient's life. If there was ever a doubt as to the diagnosis or if the patient had had previous surgery, significant pelvic organ prolapse, significant insensible urine loss (ie, not related to either stress or urge), or a neurological injury, then urodynamic testing with the Medtronic's Logic G3 unit was performed. Final treatment planning occurred after urodynamics interpretation. Patients with stress incontinence, intrinsic sphincter deficiency, or a non-compliant bladder were excluded from the study. Those excluded represented only 4% to 5% of the patients studied.

The Overactive-Bladder-Validated 8-Question Screener (OAB-V8) for overactive bladders (see Table 1) was provided to patients at the first and all subsequent visits. Patients also filled out bladder diaries at the beginning, middle, and end of treatment.

Constipation contributes to the number of incontinence episodes in urge incontinence. Hence, constipated patients were treated with increased fluids, increased exercise, and a high-fiber diet. In addition, the laxative Senokot C was prescribed at 2 pills in morning and 2 at night. Miralax was ordered for a slow colonic transit time, as evidenced by pellet-shaped stool; Lactulose was given for fecal impaction.

All patients were treated with the usual dietary modifications recommended for urge incontinence symptoms: the avoidance of caffeine in all forms as well as carbonated and acidic foods (see Table 2). Patients tested themselves on frequently ingested acidic foods to determine whether or not they were bladder irritants for them. When bladder-irritating foods were identified, patients stopped the acidic food for 4 to 7 days, depending on the frequency of intake of that food. If they then improved after testing, they eliminated that food from their diet. Nurses coached the patients in behavioral modification, particularly trying to increase their voiding intervals and to help the patients adhere to their dietary restrictions.

Therapeutically, patients were treated on a weekly basis for 12 weeks with traditional pelvic floor muscle rehabilitations that include exercises, biofeedback, and electrical stimulation. PFMR therapies were performed by 2 RN-BSNs and evaluated by a physician.

For the first 6 weeks, electrical stimulation was to the pudendal nerve (100-Hz neuromodulation) and for the second 6 weeks to the hypogastric nerve (10-Hz neuromodulation). Both used the Hollister Evadri bladder control system equipment (see

Table 1. Overactive-Bladder-Validated 8-Question Screener						
How bothered have you been during the daytime hours?	Not at all	A little bit	Somewhat	Quite a bit	A great deal	A very great deal
1. Frequent urination during the daytime hours?	0	1	2	3	4	5
2. An uncomfortable urge to urinate?	0	1	2	3	4	5
3. A sudden urge to urinate with little or no warning?	0	1	2	3	4	5
4. Accidental loss of small amounts of urine?	0	1	2	3	4	5
5. Nighttime urination?	0	1	2	3	4	5
6. Waking up at night because you had to urinate?	0	1	2	3	4	5
7. An uncontrollable urge to urinate?	0	1	2	3	4	5
8. Urine loss associated with a strong desire to urinate?	0	1	2	3	4	5
Are you male? <input type="checkbox"/> Yes <input type="checkbox"/> No	If male add 2 points to your score					
Please add up your responses to the questions above	_____					
If your score is 8 or greater, you may have an overactive bladder. There are effective treatments for this condition. You may talk to a healthcare professional about your symptoms.						

Table 2. Acidic Foods To Be Tested by Patient for Incontinent Response	
All alcoholic beverages	Guava
Apples	Peaches
Apple juice	Pineapple
Cantaloupes	Plums
Chiles/Spicy foods	Strawberries
Citrus fruits	Tomatoes
Cranberries	Vitamin B complex
Grapes	White vinegar
Dietary Restrictions: Caffeine in any form and carbonation (absolute for both—no need to test)	

Figure 1). For this technique, a probe was inserted into the vagina and the pulse amplitude turned up from 0 in 5 second intervals. The goal was for the patient to feel sustained contractions of the pelvic floor muscles at 100 Hz (pudendal nerve stimulation) and a comfortable tingling at 10 Hz (hypogastric nerve stimulation). The pulse width was 1. The pulse type was balanced, biphasic, and without a DC component. The treatment duration was 30 minutes.

Later on the same day of every PFMR treatment, so for the full 12 weeks, all patients received PTNS for 30 minutes, as described above. The physician performed all of the PTNS treatments and interpreted the urodynamic results.

Also as part of the treatments, patients applied either vaginal estrogen cream or pomegranate oil to vaginal tissues 3 times per week to optimize bladder and pelvic floor muscle functions. Pomegranate oil was given to any patient who had or was in a high-risk category for breast cancer as the oil is rich in conjugated linolenic acid, a strong phytoestrogen that is totally safe for breast cancer patients.¹⁵

During therapy the physician and nurses monitored

patients closely and communicated with each other as to each patient's progress. All patients were followed up in the office at 3 months and 6 months, then every 6 months thereafter. Median follow-up of the 94 patients is now 20 months.

The criteria for successful treatment were an absence of incontinent episodes (dry) and an OAB-V8 score less than 8, indicating no overactive bladder.¹⁶

Results

After 12 weeks of treatment, 83 of the 94 patients in the study, or 88%, achieved a totally dry status and an OAB-V8 score of less than 8. The remaining 11, or 12% of patients had a mean improvement in their incontinence episodes of 81%. Of these 11, urge-incontinence episodes decreased from a mean of 2.8 per day to 0.53 per day and none improved less than 70%. All 94 patients felt that the treatment had significantly improved their quality of life.

Of the 83 patients diagnosed as dry at the study's end, 6 later returned for their 3- to 6-month follow-up visits with relapses of their incontinence. None of these patients were doing their exercises as instructed, and all 6 were consuming small amounts of caffeine and acidic foods. After reeducation, all of these patients were fully continent at a repeat visit 6 months later and did not have overactive bladders. All are still continent with a mean follow-up of 16 months. No patient has required additional treatment.

There were no infections, bleeding, or other adverse events in any of these 94 patients. One minor adverse event occurred: following a treatment, 1 patient had tingling in her leg for 1 day.

Discussion

We believe that 1 of the main underlying pathologies contributing to urinary-urge incontinence for the overwhelming majority of urge-incontinent patients is a weak pelvic floor. In fact, we have now treated more than 300 women with urge incontinence and not a single patient had any significant pelvic

floor strength (assessed by a finger-squeeze test at physical examination). In this particular study, all 94 of the patients with urge incontinence had either no pelvic floor strength whatsoever or extremely minimal strength (<10% of normal).

Rehabilitating the pelvic floor with PFMR, including electrical stimulation of both pudendal and hypogastric nerves, allows for restoration of the reflex arc, whereby a contraction of the pelvic floor muscles will inhibit the detrusor muscle by a sacral reflex, quieting the bladder.⁶

Pelvic floor electrical stimulation at 100 Hz directly contracts pelvic floor muscles. It also contracts the pelvic floor musculature a second time through pudendal nerve afferents going to the sacral neurological complex. Efferent pudendal nerves then return to the pelvic floor musculature, producing a second contraction. There is also reflex stimulation (cross talk between the nerves), which provides a wider spread of muscle activation.¹⁷⁻¹⁹

Quieting the bladder (detrusor muscle) through the cholinergic pathways is accomplished with electrical stimulation at 10 Hz, which operates through reflex mechanisms that stimulate hypogastric efferent nerves through the pudendal nerve and thus inhibit the bladder.¹⁷⁻²⁰ Electrical stimulation is contraindicated in pregnancy or with urinary tract infections and in patients with impaired cognition.

The second aspect of our combined treatment, PTNS, is also a successful neuromodulation therapy for urge incontinence and overactive bladder, but this time through stimulation of the tibial nerve.¹³

For urge incontinence, in 1 study the success rate for PTNS alone was 70%, with 46% of these patients cured (dry).²¹ According to Uroplasty, Inc, the manufacturers of Urgent PC, the PTNS device used for this study, researchers performed a long-term PTNS study to submit as data for their FDA device approval. After using PTNS, 45% of patients were completely dry and the remaining patients achieved a 75% reduction in their incontinent episodes. As for the success (dry) rates for PFMR, these are only from 30% to 33%.⁸⁻¹¹ In this prospective trial that combined both treatments, the success (dry) rate was 88% (see Table 3).

	Cure (Dry) Rates at Study's End
PFMR ⁸⁻¹¹	30.2 % - 33 %
PTNS ^{8,21}	46%
Combination*	88%
PFMR & PTNS	
* Data from current study	

To date, medical investigation has found very little long-term effective treatment, and rarely long-term cures, for urge incontinence.⁶

Compared with the above-described studies, the combination of neuromodulation of the pudendal and hypogastric nerves with pelvic floor exercises and biofeedback and PTNS

has an additive and perhaps even a synergistic effect. These 2 treatment modalities work through completely different mechanisms of action: The muscarinic cholinergic system is treated through the pudendal nerve, and the parasympathetic and sympathetic neurological pathways are treated with neuromodulation of the tibial nerve. This treatment combination addresses all 3 of the neurological pathways to the bladder while also strengthening the urethra.

For urge-incontinent patients, a strong pelvic floor is a key element in achieving successful treatment with lasting duration. We are the first center in the world to combine the traditional PFMR techniques of pelvic floor exercises, biofeedback, and electrical stimulation (neuromodulation of the pudendal and hypogastric nerves) with PTNS. A frequent problem in comparing results of different therapies at other institutions is that most studies utilize the International Continence Society definition of cure, which is a greater than 80% improvement. Our more strict definition of cure being completely dry and an OAB-V of less than 8 actually places the odds against our findings.

All patients are instructed to return for re-evaluation at the first sign of any change in their voiding pattern: ie, frequency, nocturia, or urgency. We feel that close follow-up is essential in the nonsurgical treatment of urinary incontinence. Without that, patients may otherwise return to their pretreatment diets and voiding behavior. A real concern, of course, is their continuation of the pelvic floor exercises as taught at the center. We have now added vaginal manometry, which measures pelvic floor strength, to the follow-up visits to emphasize the importance of these exercises to the patients. We see patients every 3 months for the first year and then every 6 months for as long as they live in Arizona or are willing to return. They are asked never to wait for an incontinence episode to call the office. However, as noted, only 6 patients in this series have relapsed, and they were dry again with only reeducation as to diet and exercises and needed no further therapy.

Conclusions

Our results in this study of conservative, minimally invasive treatment of urinary-urge incontinence are impressive. Combining PTNS with PFMR consisting of pelvic floor exercises, biofeedback, and electrical stimulation of both pudendal and hypogastric nerves to treat urge incontinence may someday completely change the management of urge incontinence. Long-term follow up as well as confirmatory studies are needed.

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