



Subjective and objective responses to PTNS and predictors for success: a retrospective cohort study of percutaneous tibial nerve stimulation for overactive bladder

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Abstract

Introduction and hypothesis We investigated the objective improvements in overactive bladder (OAB) symptoms in patients undergoing percutaneous tibial nerve stimulation (PTNS) and predictive factors of patient satisfaction.

Methods In this single-center retrospective cohort study at a tertiary urogynecology center, we identified all female patients who underwent PTNS therapy from 1 October 2007 – 1 January 2016 and followed them from their initial visit through medication therapy and PTNS treatments. Patients who tried at least one medication prior to starting PTNS therapy and completed at least one PTNS visit were included. Baseline demographic data, urinary data, and details of medication and PTNS therapy sessions were collected from records through chart review. Paired or two-sample *t*-tests were used to compare changes over time or groups. Bivariate and multivariable logistic regression were performed.

Results Two hundred thirteen patients underwent PTNS therapy and 183 patients met the criteria. Overall patients were able to decrease voiding frequency by 1 h, decrease nocturia episodes by 0.8, and decrease urge incontinence episodes with PTNS therapy by ten episodes per week ($p = 0.02$). Patients who continued OAB medications did not have additional improvements compared with patients who did not continue OAB medications during PTNS. Overall, 25.4% (43/169) patients reported $\geq 75\%$ improvement during PTNS therapy, and 61.5% (104/169) reported $\geq 50\%$ improvement. When evaluating predictive factors of $\geq 50\%$ overall improvement, the number of PTNS sessions increased odds of subjective success (OR = 1.8, $p = 0.004$). Other factors were not significant predictors of subjective PTNS success.

Conclusions PTNS can provide both objective and subjective improvements for patients who do not respond to OAB medication therapy.

Keywords Overactive bladder · Percutaneous tibial nerve stimulation

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Introduction

Overactive bladder syndrome (OAB) is a common and bothersome condition for women across the US with a reported prevalence of 8–29% [1]. The International Continence Society defines OAB as the presence of “urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of a urinary tract infection or other obvious pathology” [2]. Treatment of OAB has become commonplace among primary care physicians, gynecologists, urologists, and urogynecologists. Symptom improvement in women increases quality of life and productivity.

The American Urological Association (AUA) identifies first-line treatment of OAB as behavioral therapy including bladder retraining and modifying dietary and liquid consumption. They have revised their recommendation and now include concomitant medication therapy with behavioral therapy based on literature suggesting that simultaneous use of medication and behavioral therapy results in greater improvement in symptoms and patient satisfaction with therapy [3, 4]. Third-line therapies include onabotulinumtoxinA therapy of the bladder wall, sacral neuromodulation with the Interstim® System, and percutaneous tibial nerve stimulation (PTNS) [3]. Multiple studies demonstrate that PTNS represents a beneficial therapy for OAB symptoms, both in patients who have not found success with OAB medications or behavioral therapy and in those who cannot tolerate the side effects of anticholinergic OAB medications. While studies have compared treatment types, they have not looked at how patients who progress to PTNS therapy benefit over their own experience with OAB medications. Many patients also continue to take OAB medications while pursuing PTNS therapy, and this benefit has not been evaluated.

Our primary objective was to compare changes in urinary frequency, nocturia, and urge incontinence episodes in patients after 12 weeks of PTNS therapy with changes during OAB medication therapy. We chose our comparison group for PTNS therapy as historical controls during OAB medication therapy to better answer the clinical question of what objective and subjective improvements PTNS therapy adds to OAB treatment. Patients who do not respond to OAB medication treatment may represent a group separate from patients who do respond to medication treatment. In counseling patients, providers are often asked if the next step in therapy will benefit a particular patient, in this case patients who did not respond well to OAB medication therapy. In our study we seek to better answer this question.

Our secondary objective was to compare urinary frequency, nocturia, urge incontinence episodes, and overall satisfaction with PTNS therapy between patients who concurrently continued OAB medication therapy versus those who did not. Finally, we sought to identify predictors of success with PTNS

treatment after 12 sessions based on symptom severity, medication use, and baseline demographics, surgical history, and comorbidities.

Materials and methods

We conducted a retrospective cohort study of patients who presented to North Shore University Health System Urogynecology Practice from 1 October 2007 – 1 January 2016 for OAB treatment. At their initial visit patients were asked baseline symptoms including urinary frequency, nocturia episodes, number of urge incontinence episodes per week, basic demographic information, and medical and surgical history. Patients were then asked to try conservative therapy and/or concurrent OAB medication therapy. After trying at least two medications with unsatisfactory results, patients were offered PTNS therapy, onabotulinumtoxinA therapy, or sacral neuromodulation with Interstim® System therapy. Patients who chose to pursue PTNS therapy were then scheduled for a series of 12-weekly 30-min sessions with a urogynecology nurse.

When a patient presents for PTNS therapy, a urogynecology nurse, who has been trained by both nursing and physician staff, places a small needle in the trigger spot superior and medial to the medial malleolus near the ankle and adjusts the stimulation voltage until the patient feels some muscle stimulation (Urgent PC, Uroplasty, Minnetonka, MN, USA). Weekly sessions for a 12-week treatment schedule are most frequently used by urogynecology practices in the US. There have been studies investigating more frequent therapy for a shorter duration in time, three times a week for a 4-week duration, and for a shortened duration to 6 weeks with good effect. Currently, we have found that patients find it difficult to come more than once a week and have good effects with the traditional 12-week course used here [5].

Patient charts were identified from the electronic medical record by selecting for CPT code 64566-Percutaneous tibial nerve stimulation. All patients who underwent PTNS therapy from 1 October 2007 – 1 January 2016 were included in the study. Chart review was then conducted to obtain their baseline data, medication trial information, and PTNS treatment data. Baseline data were collected and included date of birth, visits and treatment dates, urinary frequency (hours between daytime voids), nocturia (episodes of awaking at night to void), urge incontinence episodes per week, self-reported percentage improvement in symptoms, history of prior surgery for pelvic organ prolapse or incontinence, prior use of onabotulinumtoxinA or Interstim® System therapy, medical problems such as diabetes or hypertension, urodynamics diagnosis if they had testing performed, and cystoscopy diagnosis if performed. At every physician and nurse visit for PTNS therapy patients were questioned about subjective overall

improvement by asking, “How much have you improved from baseline on a scale of 0–100%?” This was the self-reported percentage improvement. Patients also filled out validated questionnaires but the data were inconsistent and so not used for this study. Medication data including the medication, dosage, and duration used as well as side effects were also captured. Information about the PTNS sessions such as duration and intensity of PTNS settings and concomitant OAB medication use was recorded. All patients had a diagnosis of OAB. Patients who completed at least one PTNS visit and tried at least one OAB medication were included in the study. No patients were excluded if they met the above criteria. This study was approved by the North Shore University Health Systems Institutional Review Board (EH 16-274).

Our primary outcome measure was change in urinary frequency, nocturia, and urge incontinence episodes in patients undergoing PTNS therapy compared with the change they had while on OAB medication therapy. We chose historical controls because we felt that patients who have failed multiple medication therapies were not similar to patients who persisted on medical therapy, nor were they similar to patients who chose onabotulinumtoxinA or sacro neuromodulation (Interstim® System) therapy in their perceptions of success of treatment. Many women who are averse to perceived advanced interventions will stop therapy or persist on medication management despite dissatisfaction with the success rates [6].

Our secondary outcome measure compared urinary symptoms of patients who chose to remain on OAB medications during PTNS therapy with those who did not. Symptoms included urinary frequency, nocturia, and urge incontinence episodes of those patients as measured by how often they voided during the daytime, the number of times they awoke at night to void, and the number of incontinence episodes with urge in a 1-week period. We then evaluated patient baseline characteristics including prior pelvic surgery, medication history, and indicators of microvascular disease (diabetes and hypertension) to develop a predictive model for success with PTNS treatments.

In our power calculation we used baseline improvement data from Peters et al.’s randomized controlled trial comparing PTNS therapy to medication therapy with tolterodine. This is one of the few studies comparing PTNS to medication therapy [7]. They reported 79.5% success (defined as a 50% reduction in symptoms) with PTNS therapy and 54.8% with tolterodine. Using a two-sided alpha level of 0.05 and 80% power with a paired-proportions test (McNemar’s test, assuming a correlation between paired observations of 0.1) results in 54 patients needed, which we were able to exceed. While their study design is different from ours, there is no prior known study that compares PTNS treatment outcomes with outcomes during medication therapy within the same patient.

Continuous variables were summarized as mean and standard deviation. Categorical variables were summarized as frequency and percentage. Paired *t*-tests were used for assessing

within-person changes over time in objective OAB outcomes. Chi-square tests or Student’s *t*-tests were used for comparison between groups. Bivariate and multivariable logistic regression models were fit to examine predictors of PTNS therapy success, defined as at least 50% improvement at the end of 12 weeks of PTNS therapy. Changes in self-reported improvement over the 12 PTNS sessions were further explored using mixed-effects logistic regression with PTNS visit as a categorical fixed effect and a random subject effect. Correlations among improvement and urinary frequency, nocturia, or urge incontinence were determined based on the approach described by Bland and Altman to account for the multiple observations per patient [8]. Statistical analysis was performed with Stata 15 (StataCorp, College Station, TX) software. $p < 0.05$ was considered statistically significant.

Results

Two hundred thirteen patients were identified from the electronic medical record by CPT code who underwent PTNS therapy from 1 October 2007–1 January 2016. Of all patients identified, 183 met the inclusion and exclusion criteria. All 183 patients were included in the analysis. Overall, the average age of patients was 74 years, and 83% identified as White or Caucasian. On average, women had delivered 2–3 children and were overweight when categorized by body mass index (BMI) categories. While most patients had a history of pelvic surgery, less than half had undergone prolapse or incontinence surgery. Overall patients voided every 1.6 h, awoke 2–3 times per night to void, and had 21 urge incontinence episodes every week, averaging 3 urge incontinence episodes every day. Before starting PTNS therapy patients had tried on average 2–3 OAB medications for 34 months (almost 3 years). When evaluating side effects of OAB medications, 123/183 (67%) of patients reported at least one side effect of medications. Of the 123 patients with side effects, 72% reported dry mouth, 10% reported dry eyes, and 29% reported constipation (Table 1).

For patients who underwent PTNS therapy without simultaneous use of OAB medications and those who underwent PTNS with simultaneous use of OAB medications, there were no significant differences in demographic factors or medical comorbidities (Table 1). Additionally, baseline urinary symptoms, the number of OAB medications tried, and the duration of OAB medications prior to PTNS were not different between these two groups (Table 1).

From initial presentation to the end of their medication trial, patients demonstrated worsening symptoms including decreased time between voids, increased nocturia episodes, and increase in urge incontinence episodes per week. Compared with their changes in urinary symptoms while on OAB medication therapy, patients who underwent PTNS therapy had statistically significant improvement in urinary frequency,

Table 1 Baseline characteristics

Characteristic	All patients mean (SD)	PTNS therapy only mean (SD)	PTNS therapy and OAB medication use mean (SD)	<i>p</i> value*
Age at initial visit	73.7 (11.4)	73.7 (10.6)	73.7 (12.1)	1.00
Gravity	2.9 (2.1)	2.6 (1.5)	3.1 (2.5)	0.15
Parity	2.4 (1.7)	2.3 (1.3)	2.6 (2.0)	0.30
BMI at initial visit	28.0 (6.5)	27.9 (6.8)	28.0 (6.3)	0.98
Baseline Urinary frequency (voids every x hours)	1.6 (1.1)	1.7 (1.3)	1.6 (0.9)	0.66
Baseline Nocturia (voids x times per night)	2.7 (2.1)	3.0 (2.5)	2.4 (1.6)	0.08
Baseline urge incontinence episodes (x times per week)	21.1 (31.4)	23.9 (38.7)	18.7 (23.5)	0.32
Characteristic	All patients N (%)	PTNS therapy only N (%)	PTNS therapy and OAB medication use N (%)	<i>p</i> value**
History of pelvic surgery	113 (62%)	50 (57%)	63 (66%)	0.26
History of prolapse surgery (among those with any pelvic surgery)	28/113 (25%)	14/50 (28%)	14/63 (22%)	0.48
History of incontinence surgery	46 (25%)	21 (24%)	25 (26%)	0.77
History of diabetes	24 (13%)	11 (13%)	13 (14%)	0.86
History of hypertension	80 (44%)	41 (47%)	39 (41%)	0.38
Characteristic	All patients mean (SD)	PTNS therapy only mean (SD)	PTNS therapy and OAB medication use mean (SD)	<i>p</i> value*
Number of OAB medications tried prior to PTNS therapy	2.5 (1.4)	2.4 (1.3)	2.5 (1.5)	0.58
Duration of OAB medication treatment prior to PTNS therapy (months)	34.3 (27.6)	34.1 (27.2)	34.4 (28.1)	0.93
Number of PTNS therapy sessions completed	11.2 (2.3)	11.1 (2.2)	11.3 (2.4)	0.57

*Comparison using Student's *t*-test

**Comparison using chi-square test

decreased nocturia episodes, and fewer urinary urge incontinence episodes. Overall patients were able to decrease their voiding frequency by approximately 1 h with PTNS therapy, decrease nocturia episodes by 0.8, and decrease their urge incontinence episodes with PTNS by about ten episodes per week ($p = 0.02$) (Table 2). Patients who continued OAB medication therapy during PTNS did not have any additional improvements in urinary frequency, nocturia, or urinary urge incontinence episodes compared with patients who did not continue OAB medications during PTNS therapy (Table 3).

Overall, 25.4% (43/169) of patients reported $\geq 75\%$ improvement during PTNS therapy, and 61.5% (104/169) reported $\geq 50\%$ improvement. We then sought to investigate

predictors of success with PTNS treatment in patients who had poor success with behavioral and OAB medication therapy. Only the number of PTNS sessions was predictive of $\geq 50\%$ self-reported improvement in univariate analysis when looking at all baseline characteristics. In multivariable analysis including number of PTNS visits, age, baseline urinary frequency, nocturia, and urge incontinence episodes, the number of PTNS sessions attended remained predictive of treatment success (Table 4).

While there was an overall trend of increased satisfaction with increasing number of PTNS visits, there was an apparent jump between the 6th and 7th PTNS session as well as from the 9th to 10–12th visit. There was no clear plateau effect for

Table 2 Comparison of improvement in urinary frequency, nocturia, and urge incontinence episodes with historical controls

Characteristic	Change with OAB medications Mean (SD)	Change with PTNS therapy Mean (SD)	<i>p</i> value*
Urinary frequency (voids every x hours)	-0.3 (1.1)	0.9 (2.4)	< 0.001
Nocturia (voids x times per night)	0.1 (1.5)	-0.8 (1.6)	< 0.001
Urge incontinence episodes (x times per week)	7.1 (40.2)	-9.1 (17.8)	0.02

*Comparison using paired *t*-test

Table 3 Comparison of improvement in urinary frequency, nocturia, and urge incontinence episodes between patients who stopped and who continued OAB medication therapy during PTNS therapy sessions

Characteristic	PTNS therapy only Mean (SD)	PTNS therapy and OAB medication use Mean (SD)	<i>p</i> value*
Change in urinary frequency (voids every x hours)	0.6 (1.1)	1.0 (2.5)	0.15
Change in nocturia (voids x times per night)	-1.1 (2.2)	-0.8 (1.2)	0.40
Change in urge incontinence episodes (x times per week)	-11.7 (26.9)	-10.3 (21.4)	0.72

*Comparison using Student's *t*-test

number of PTNS sessions needed to achieve $\geq 50\%$ or $\geq 75\%$ improvement. Significant within-person correlations were found between self-reported improvement and frequency ($r = 0.35$, $p < 0.001$), nocturia ($r = -0.35$, $p < 0.001$), and urinary urge incontinence episodes ($r = -0.31$, $p < 0.001$) strengthening this association.

Standard PTNS therapy at our institution includes 12 weekly visits; 100/183 (55%) patients had > 13 visits indicating PTNS monthly maintenance therapy or repeat sessions of 12 visits. No predictive factors for participating in more than 13 visits were identified, including age ($p = 0.19$), BMI ($p = 0.09$), diabetes mellitus ($p = 0.62$), hypertension ($p = 0.70$), number of OAB medications previously tried ($p = 0.87$), or history of incontinence procedures ($p = 0.70$). Overall, patients reported both objective and subjective improvement in OAB and urge incontinence symptoms with PTNS therapy over and above OAB medication therapy.

Discussion

Our study noted that patients who had little improvement in their urinary frequency, nocturia, and urge incontinence while taking OAB medications found benefit with PTNS therapy. We also found no difference in outcomes whether patients continued taking OAB medications or stopped them during PTNS therapy. We looked at this comparison because many of our patients insist on remaining on OAB medications while undergoing PTNS therapy despite prior lack of success with OAB medications. This finding can be a useful tool to better

counsel patients in the future. Patients who had no improvement in OAB medications may represent a subset of all OAB patients who process or respond to OAB medications differently from patients who have a positive response to medication therapy. Further research is needed in the area. The number of PTNS sessions was the only predictor for success ($\geq 50\%$ self-reported improvement) when also considering baseline characteristics and urinary symptoms, microvascular disease, and prior prolapse and incontinence surgery. Propst et al. reported an increase after the fourth PTNS session, which we did not see in our data. [9].

Peters et al. conducted a randomized controlled trial comparing OAB outcomes of PTNS with sham treatment. They evaluated changes in urinary frequency, urgency, urge incontinence episodes, and a global response assessment. They found that 54.5% of patients who underwent PTNS treatment reported moderate or markedly improved response to treatment compared with 20.9% who completed sham treatment. While they did note a statistically significant difference in urinary urgency, frequency, and urge incontinence episodes with PTNS treatment compared with sham treatment, the clinical effect was much smaller than improved satisfaction and perceived improvement in symptoms [6]. We were able to show similar overall satisfaction rates as well as similar, if not greater, objective improvements during PTNS therapy. On average, our patients were almost 10 years older than those studied by Peters. This older age cohort may benefit from ongoing interaction with our nursing staff.

Peters et al. also conducted one of the few randomized control trials comparing PTNS with medication therapy for

Table 4 Multivariable logistic regression predicting PTNS success ($\geq 50\%$ improvement)

Characteristic	Odds ratio (OR)	95% confidence interval	<i>p</i> value
Number of PTNS sessions completed	1.80	1.20–2.69	0.004
Age	1.00	0.97–1.03	0.94
Baseline urinary frequency (voids every x hours)	0.78	0.55–1.11	0.17
Baseline nocturia (voids x times per night)	0.95	0.77–1.16	0.62
Baseline urge incontinence episodes (x times per week)	1.01	0.99–1.02	0.28

OAB. They found that 79.5% of patients who underwent PTNS therapy reported improvement compared with 54.8% of patients on tolterodine, but no differences between the groups in urinary urgency, frequency, and urge incontinence episodes were observed [10]. Vecchioli-Scaldazza in 2012 compared solifenacin succinate with PTNS treatment in a randomized crossover study of 40 patients who received both treatments. They found PTNS to have a greater decrease in urinary urgency, frequency, and urge incontinence episodes compared with solifenacin treatment, with greater perceived improvement in treatment response [11]. The above studies show improved global satisfaction in treatment above changes in urinary urgency, frequency, and urge incontinence episodes [12, 13]. Our results showed improvement in objective and subjective measures with PTNS over OBA medication therapy, similar to the study by Vecchioli-Scaldazza. This may be because we compared patient improvement in PTNS with their own changes during OAB medication therapy. All patients in our study were dissatisfied with their OAB treatment. Our study may more accurately reflect current practice in moving patients along the AUA OAB treatment algorithm, providing a more clinically useful comparison.

Few studies capture granularity of changes during OAB medication therapy, and we were able to capture changes in dose, reason for change, and duration of medication use because of our electronic medical record and because patients are followed for many years in our practice. We also choose to compare improvements on PTNS therapy with improvements during medication therapy as this is what we see in clinical practice. Because we followed patients over time and compared them with their own success on OAB medication therapy, our results are generalizable to many urogynecology practices in the US and better represent the population of patients undergoing PTNS therapy.

Limitations of the study are that it is retrospective in nature. We were unable to access data that were not present in the medical record or collected at that time. Our outcome measures were patient reported and not based on a standardized OAB questionnaire. We choose to proceed with the study despite the lack of standard questionnaire data as we felt that our experience and results were valuable to practicing urogynecologists and our data captured reflect the overall feeling of benefit that may not be captured in a questionnaire. Clinic documentation during PTNS therapy sessions by our nursing staff was standardized prior to the time of data capture, whereas physician visits were not standardized when patients were trying OAB medications. Changes in medication were also made over the phone outside of the physician visits and were often due to insurance changes and intolerance of medication due to side effects, and they were sometimes inconsistently documented. While our chart review included telephone calls and medication list review, some data may have been lost. While some of our data were inconsistent, standardization of nursing PTNS documentation ensured accurate and consistent data capture during

PTNS therapy. On average patients in our cohort spent 2 years trying OAB medications prior to progressing onto PTNS therapy. Patients aged as they continued therapy making it possible that their treatment failure was due to worsening aging and possible progression of OAB symptoms rather than poor response to OAB medication treatment alone.

We found both objective and subjective improvements in urinary frequency, nocturia, and urge incontinence with PTNS therapy in patients who were dissatisfied with OAB medication therapy. Additionally, we found that the number of PTNS visits was predictive of $\geq 50\%$ improvement in OAB and urge incontinence symptoms. Interestingly, only 55% of our cohort continued onto maintenance PTNS therapy. The reasons for this could be due to problems with transportation, lack of ongoing insurance coverage, dissatisfaction of therapy once the 12 initial visits had been completed, or not continuing with OAB treatment for other reasons. Future research is needed to better elucidate the biological mechanism of PTNS, reasons for stopping OAB therapies overall, and the role of care pathways to enable more patients to access PTNS therapy sooner after initiating treatment for OAB.

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Compliance with ethical standards

Conflicts of interest None.

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