

PROSPECTIVE STUDY TO EVALUATE QUALITY OF LIFE WITH THE NURO™ PERCUTANEOUS TIBIAL NEUROMODULATION SYSTEM IN DRUG NAÏVE PATIENTS WITH OVERACTIVE BLADDER SYNDROME

Kathleen Kobashi¹, Eric Margolis², Peter Sand³, Steven Siegel⁴, Salil Khandwala⁵, Diane Newman⁶, Victor Nitti⁷, Scott MacDiarmid⁸, Elizabeth Michaud⁹, Fangyu Kan⁹

1. Virginia Mason Medical Center, 2. Urologic Research and Consulting LLC, 3. NorthShore University Health-System, 4. Metro Urology, 5. Advanced Urogynecology of Michigan PC, 6. University of Pennsylvania, 7. NYU School of Medicine, 8. Alliance Urology Specialist, 9. Medtronic

Objective

To evaluate change in quality of life (QoL) after 12 weeks of percutaneous tibial neuromodulation (PTNM) therapy in drug-naïve subjects with overactive bladder (OAB) syndrome.

Background

The NURO™ system delivers electrical pulses through a needle to stimulate the afferent fibers of the tibial nerve that runs posterior to the medial malleolus and extends to the sacral nerve plexus.



RESET is a prospective, multicenter, single arm study. Subjects with symptoms of urge urinary incontinence (UUI) who had not tried an OAB medication were included.

Study Design and Methods

Eligible subjects underwent 12 weekly PTNM sessions, utilizing the NURO system. Voiding diary and questionnaires were collected at baseline and after PTNM session #1, #4, #8 and #12. Study approval was given by institutional review boards and all subjects provided informed consent.

Change in QoL from baseline through PTNM session #12 was assessed utilizing the Overactive Bladder Symptom Quality of Life Questionnaire (OAB-q), which measures health-related QoL (HRQL) and subscales of Concern, Coping, Sleep, Social as well as symptom bother. Paired t-test or Wilcoxon signed-rank test was used to evaluate the change after testing for data normality by calculating Shapiro-Wilk W statistic.

Safety was evaluated by the collection of adverse events related to the device, procedure and therapy (device-related).

Results

One hundred and fifty-four (154) subjects enrolled in the study, of which 120 met study criteria and received PTNM. Demographics of treated patients are listed in the Table, and QoL from baseline through PTNM session #12 are shown in the Figures.

Demographics	All treated (n=120)
Gender, female	86%
Race, white	88%
Mean age at consent (years)	64.8 ± 11.6
Years since diagnosis	3.4 ± 5.1
Baseline UUI episodes/day* (n=119)	3.5 ± 2.5
Baseline voids/day** (n=86)	11.5 ± 2.9

Plus minus values are mean ± standard deviation.

*n=119 (1 subject did not provide evaluable diary at baseline).

**Summarized for urinary frequency (UF) subjects with at least 8 voids/day at baseline (n=86)

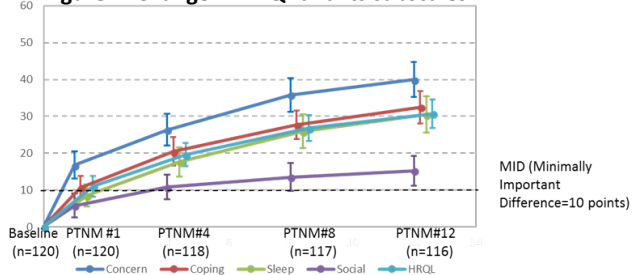
Efficacy and safety (reported previously):

- Significant improvements in efficacy over time through 12 weeks of PTNM therapy
- At 12 weeks, reduction of 2.4 ± 2.1 UUI episodes/day was observed ($p < 0.0001$).
- At 12 weeks, reduction of 1.7 ± 2.5 voids/day was observed ($p < 0.0001$) for UF subjects.
- An average of 11.6 PTNM sessions per subject
- No serious adverse device effects or unanticipated adverse device effects
- Most common adverse events reported: medical device site pain (3.3%, 4/121); pain in extremity (3.3%, 4/121).

Note: One subject received PTNM therapy, but did not meet eligibility criteria. This subject was not included in efficacy or QoL analysis, but was included in safety analysis.

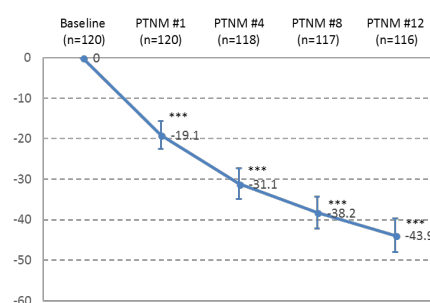
- HRQL and its subscales (Concern, Coping, Sleep, Social) showed significant improvements from baseline at PTNM sessions #1, #4, #8, and #12 (all $p < 0.0001$). Average improvements from baseline for Concern, Coping, Sleep, and HRQL were 3 to 4 times greater than the Minimally Important Difference (MID)¹ at PTNM session #12 (Figure 1).
- Symptom bother scale showed significant improvements from baseline at PTNM sessions #1, #4, #8, and #12 (all $p < 0.0001$) (Figure 2).

Figure 1: Change in HRQL and its subscales



Note: Baseline=45 (concern); 53.1 (Coping); 52.1 (Sleep); 80.4 (Social); 56.1 (HRQL). All paired tests comparing follow-up to baseline had a $p < 0.0001$. Error bars are 95% CI. A positive change indicates improvement in QoL.

Figure 2: Change in symptom bother scale



Note: Baseline=67.3. Error bars are 95% CI. *** $p < 0.0001$. A negative change indicates improvement in QoL.

Interpretation

Statistically significant improvements in QoL were demonstrated in subjects with OAB through 12 weeks of therapy.

Conclusion

Percutaneous tibial neuromodulation using the NURO system improves quality of life as well as symptoms observed in voiding diary for drug-naïve patients with OAB.