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

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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.

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.

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).

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.

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).

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.

Note:


* Significantly different from baseline (p<0.05). ** Summarized for urinary frequency (UF) subjects with at least 8 voids/day at baseline (n=86)

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).

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.

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

Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>Race</th>
<th>Mean age at consent (years)</th>
<th>Years since diagnosis</th>
<th>Baseline UUI episodes/day</th>
<th>Baseline voids/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>female</td>
<td>white</td>
<td>64.8 ± 11.6</td>
<td>3.4 ± 5.1</td>
<td>3.5 ± 2.5</td>
<td>11.5 ± 2.9</td>
</tr>
</tbody>
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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.

Figure 1: Change in HRQL and its subscales

Figure 2: Change in symptom bother scale