OM06

OVERACTIVE BLADDER TREATMENT USING A WEARABLE TIBIAL NEUROMODULATION SYSTEM WITH PHYSIOLOGIC CLOSED-LOOP CONTROL: POOLED ANALYSIS

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Objective

To evaluate the efficacy of wearable tibial neuromodulation (wTNM) with physiologic closed-loop control using electromyogram feedback signal[1] for treating symptoms of overactive bladder syndrome (OAB) after 12 weeks at 3x/week therapy sessions and at 6 months of treatment. Two clinical trials had previously shown efficacy for OAB symptoms, but there was varied dosing frequency of 1-3x per week. This pooled analysis is to evaluate a consistent 3x/week 30-minute session of wTNM therapy for broader assessment of efficacy for OAB symptoms.

Methodology

The pooled analysis population consisted of a subset of subjects from two multi-center clinical trials who conducted wTNM therapy 3x/week. The wTNM device contains physiologic closed-loop control using electromyogram feedback signal and an active mobile app to control therapy. The first was a dosing study (N=96)[2], and the second a sham-controlled trial (N=125). Efficacy was computed by tracking symptoms of micturition frequency (voids), incontinence events and urgency events through 3-day bladder diaries.[2]

Figure 1. The wTNM Device

The primary efficacy endpoint was defined as achieving at least 50% responder rate, where in a responder is a subject with ≥50% improvement in incontinence event or ≥30% improvement in voids or becoming asymptomatic after treatment. Secondary analyses included proportion of subjects returning to normal (asymptomatic) and computing individual symptom improvements.

Results

The mean symptom change was computed as the difference between daily symptoms at baseline and after treatment. Subjects (mean age of 63.0 and 94.5% female population) demonstrated significant symptom change at 12 weeks and 6 months of treatment as seen below (note: a subject may have more than one symptom).

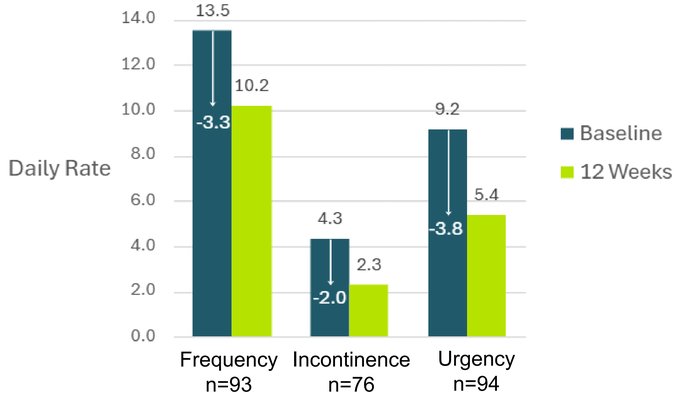

Figure 2. Symptom Reduction following 12 Weeks of treatment

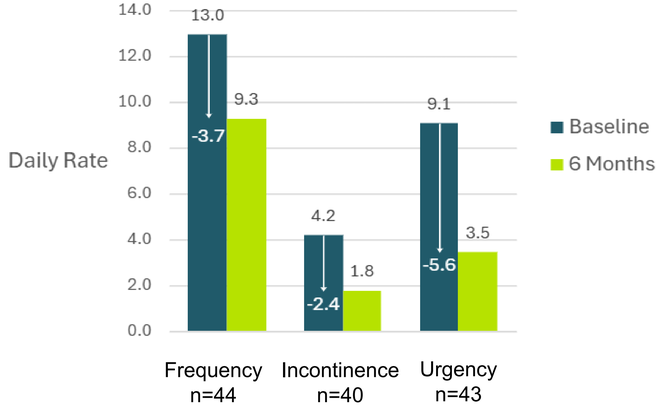

Figure 3. Symptom Reduction following 6 Months of Treatment

Results (continued)

For 102 subjects after 12 weeks, the responder rate was 77.5%, 95% CI [69.3% 85.6%] meeting the primary effectiveness criteria of ≥ 50% responder rate (p-value < 0.0001). For 49 subjects that opted to continue enrollment and follow-up in the study after 6 months, the responder rate was 73.5%, 95% CI [61.1%, 85.8%].

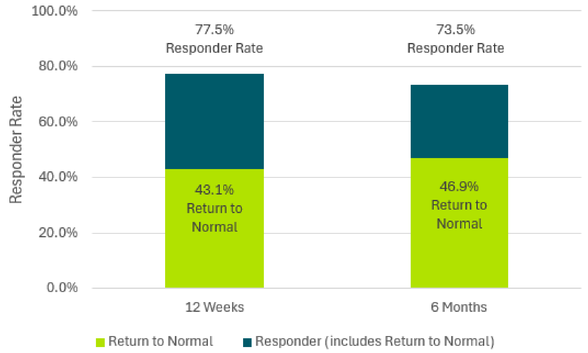

Figure 4. Responder Rate per Primary Endpoint

In addition, analysis showed 43.1% subjects, CI [33.5% 52.7%] after 12 weeks and 46.9%, CI [33.0% 60.9%] after 6 months of treatment returned to normal (RTN), i.e. became asymptomatic for voids (≤ 8 voids/day) or leaks (totally dry).

Conclusion

The wTMN device with physiologic closed-loop control when used 3x/per week for 30 minutes was shown to be an effective OAB treatment in this pooled analysis of clinical trials, with significant symptom improvement after both 12 weeks and 6 months of use.

References

1. Gerig N, Cameron T, Arora S, Spear J, Lescozec L, Zhang M. Do we need more patient-friendly treatment options for overactive bladder (OAB)?. *Neurourol Urodyn*. 2021;40(6):1433-1440. doi:10.1002/nau.24731

2. Goudelocke C, Sobol J, Poulos D, Enemchukwu E, Zaslau S, Dhir R. A Multicenter Study Evaluating the FREquency of Use and Efficacy of a Novel Closed-Loop Wearable Tibial Neuromodulation System for Overactive Bladder and Urgency Urinary Incontinence (FREEOAB). *Urology*. 2024;183:63-69. doi:10.1016/j.urology.2023.10.007