RESET STUDY OUTCOMES

Evidence from the RESET study on Percutaneous Tibial Neuromodulation (PTNM) delivered by the NURO™ system shows:

- NURO™ is an effective drug-free treatment for patients with overactive bladder (OAB), even if they have not previously tried OAB medication or are averse to medication.¹
- The importance of finishing the therapy and waiting until sessions 8–12 to determine if a patient is or will respond to PTNM therapy.

PRESENTED AT SUFU 2019

~23%

of patients who eventually responded to NURO™ first responded at week 8 or later.²

PRESENTED AT AUA 2018

~70%

reduction in UI episodes per day at completion of 12 PTNM sessions.³

PRESENTED AT AUGS 2018

~90%

reduction in the proportion of patients who reported having severe or very severe problems with their overactive bladder (OAB).³¹

FINISH THE THERAPY FOR OPTIMAL RESULTS

Results showed a trend for continued improvement in symptom relief, quality of life, and patient reported outcomes as patients completed more NURO™ sessions, and they had the best results when finishing the 12-session therapy.¹⁻⁵

Complying with the treatment for 12 sessions can improve the patient’s quality of life and decrease OAB symptoms.¹⁻⁵

Safety: There were no serious or unanticipated adverse device effects. The most common adverse events (AE) were medical device site pain (3.3%, 4/121) and extremity pain (3.3%, 4/121).

- Does your practice wait past session 6 to determine if your patient has responded to PTNM therapy?
- Do you have patients who are averse to medication for OAB?
- How might a drug-free approach to OAB help your patients?
RESET STUDY OVERVIEW

- Multicenter, single arm (all patients received NURO™ PTNM), prospective study sponsored by Medtronic
- Patients with OAB received 12 weekly PTNM sessions with the NURO™ system
- Study assessed voiding diaries, quality of life and other patient reported outcomes, and safety
- Analyses were based on patients who had data at baseline and follow-up visits

PATIENT PROFILES

- 120 patients, none of which had tried OAB medication prior to enrollment
- Mean Age: 64.8
- Mean duration of OAB diagnosis: 3.4 years
- Gender mix: 86% female

* Response defined as ≥50% improvement in UUI episodes/day vs baseline.
† Evaluated using the Patient Perception of Bladder Condition (PPBC) scale.
‡ Evaluated using the Overactive Bladder Symptom Quality of Life Questionnaire (OAB-q).

References

Indication for Use:
Medtronic NURO™ Percutaneous Tibial Neuromodulation is intended to treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Contraindications: Do not use on patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or on patients who are pregnant or planning pregnancy.

Warnings/Precautions/Adverse Events: Do not use if the skin in the area of use is compromised. Exercise caution for patients with heart problems. There were no serious or unanticipated AEs. Adverse events are typically temporary, and include mild pain, minor inflammation and bleeding near treatment site. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at professional.medtronic.com/NURO. Product technical manual must be reviewed prior to use for detailed disclosure.

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