🏆 Best in Category Prize – Overactive Bladder

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A PROSPECTIVE MULTICENTER CLINICAL STUDY EVALUATING A MINIATURIZED, RECHARGEABLE SACRAL NEUROMODULATION SYSTEM FOR THE SAFE AND EFFECTIVE TREATMENT OF OVERACTIVE BLADDER

Hypothesis / aims of study

A prospective multi-center clinical study is being conducted to evaluate the safety and performance of a miniaturized rechargeable implantable sacral neuromodulation (r-SNM) system for the treatment of patients with overactive bladder (OAB). SNM is an established therapy for the treatment of refractory idiopathic overactive bladder. However, current systems require a replacement surgery every 3-5 years due to the limited life of the non-rechargeable battery in the implantable stimulator. This study has treated 51 patients to evaluate a rechargeable implantable system that is designed to provide over 15 years of therapy. This report provides the interim outcomes of this study.

Study design, materials and methods

Fifty-one OAB patients were implanted with a r-SNM (**Figure 1)** system at 7 European sites. Patients were refractory to conservative therapy and had no history of SNM. A single procedure was performed to implant the permanent r-SNM system, using a sacral transforaminal approach to implant a tined lead in proximity of the third or fourth sacral nerve. Voiding diaries (72-hr) were completed prior to implant and at 2-weeks and 1-month post-implant to determine if patients were responders to the therapy. Therapy responders were identified as patients that experienced a ≥50% reduction in voids and/or incontinence episodes compared to baseline or a reduction in voids to less than 8 per day.

Figure 1. The Axonics r-SNM System includes a miniaturized, rechargeable implanted neurostimulator.

Results

All patients were implanted without event, including 38 females and 13 males with an average age of 51 years old (21-77 years). At baseline patients recorded an average of 14.6 ± 6.1 voids per day and 9.6 ± 5.1 incontinence episodes per day. This report includes results for patients that have reached 1-month and 3-month follow-up.

20 of 27 patients (74%) who completed the 1-month follow-up were initial therapy responders. Of the initial therapy responders, 14 patients have reached 3-month follow-up. 12 of 14 patients (86%) continue to be therapy responders at 3-months based on diary symptoms, averaging a reduction of 4.8 voids per day (± 4.5, *p<0.002, two-sided t-test) and 4.7 incontinence episodes per day (± 3.2, **p<0.001, two-sided t-test) compared to baseline (**Figure 2**).

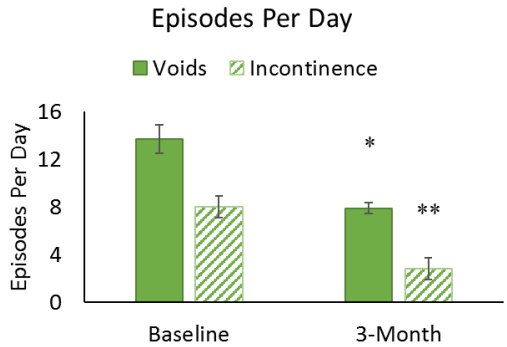

Figure 2. Diary symptoms at baseline and 3-months following r-SNM system implant. Values are average +/- standard error for 14 patients that were therapy responders at 1-month.

The initial therapy responders have experienced clinically meaningful improvements in quality of life, with improvements from baseline in the HRQL score of 31.2 points (**Figure 3**). Improvements on all quality of life subscales are well above and statistically greater than the minimally important difference of 10 points[1].

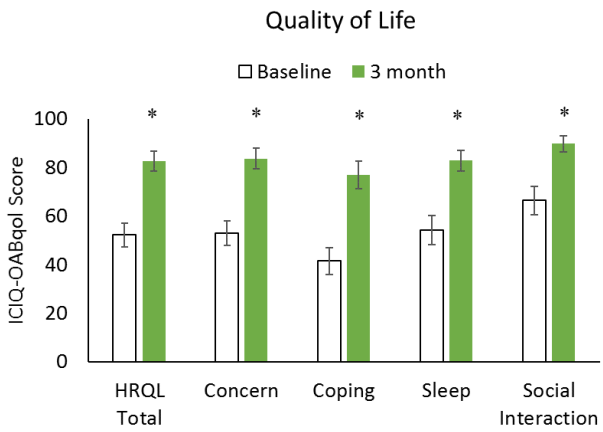

Figure 3. ICIQ-OABqol scores at baseline and 3-months. Values are mean change in score compared to baseline for patients that were therapy responders at 1-month post-implant. MID = minimally important difference. (n=13, *p<0.002)

At 3-months 86%, or 12 of 14 initial responders, were very or moderately satisfied with their therapy. Additionally, 3 of the 4 patients (75%) that were not 1-month therapy responders were very satisfied with r-SNM therapy at 3-months.

No serious device-related adverse events have been reported over 219 months of cumulative patient follow-up. One patient was explanted due to a wound infection (2% surgical intervention/explant rate). No issues or adverse events were reported related to device recharging.

Interpretation of results

The results confirm the safety and short-term efficacy of a rechargeable SNM system. A rechargeable SNM system is expected to provide significant cost-effectiveness[2] and therapeutic benefits compared to existing non-rechargeable systems.

Concluding message

Patients were safely and successfully implanted with a novel, rechargeable implantable SNM system and experienced clinically significant improvements in their symptoms.

References

1. 1. Coyne K, Matza L, Thompson C, et al. (2006) Determining the importance of change in the overactive bladder questionnaire. J Urol 176: 627-632
2. 2. Noblett K, Dmochowski R, Vasavada S, et al. (2017) Cost profiles and budget impact of rechargeable versus non-rechargeable sacral neuromodulation devices in the treatment of overactive bladder syndrome. Neurourol Urodyn 36: 727-733

Disclosures

Funding: Axonics Modulation Technologies, Inc **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov Identifier: NCT02620410 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** University College London Hospital & National Hospital for Neurology & Neurosurgery Ethical Committee; approval was obtained subsequently from the ethical committees in all participating hospitals **Helsinki:** Yes **Informed Consent:** Yes