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A PROSPECTIVE, MULTICENTER TRIAL EVALUATING EFFICACY, SAFETY AND QUALITY OF LIFE OF SACRAL NEUROMODULATION THROUGH 24 MONTHS IN SUBJECTS WITH SYMPTOMS OF OVERACTIVE BLADDER.

Hypothesis / aims of study

InSite is an ongoing, prospective, multicenter post-approval study. This analysis evaluated the therapeutic success rate and changes in quality of life (QOL) of sacral neuromodulation (SNM) with the InterStim® System at 24-months. Subjects with bothersome symptoms of overactive bladder (OAB) including urinary urge incontinence (UI) or urgency-frequency (UF), who had not exhausted all medication options (failed at least 1 anticholinergic medication and had at least 1 medication not tried) were included.

Study design, materials and methods

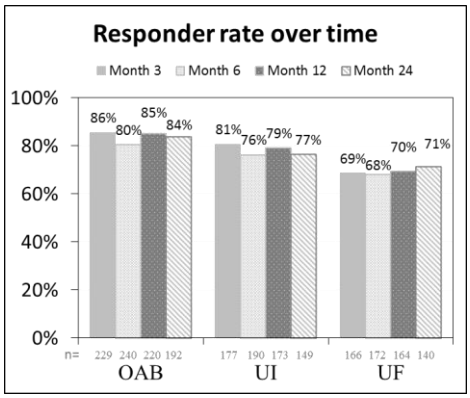
Subjects with successful test stimulation received an SNM implant. Therapeutic success was defined as a UI or UF response; for UI as a ≥ 50% improvement in average leaks/day, for UF as a ≥ 50% improvement in voids/day or a return to normal voiding frequency (<8 voids/day). QOL was evaluated using the validated disease-specific International Consultation on Incontinence Modular Questionnaire (ICIQ-OABqol) and Female/Male Lower Urinary Tract Symptom sexual function (FLUTSsex and MLUTSsex), Beck Depression Inventory II (BDI-II) and Visual Analogue Scale (VAS) for Pelvic Pain associated with urgency instruments. Therapeutic success and QOL through 24 months were evaluated for all implanted subjects with data at baseline and follow-up (3, 6, 12 and 24 months).

Results

Of the 340 subjects who went through test stimulation, 272 were implanted with SNM. For subjects implanted with the full system, 91% were female and mean age was 56.7 years. At baseline, UI subjects had 3.1±2.7 leaks/day; UF subjects had 12.6±4.5 voids/day. Subjects showed sustained therapeutic success as presented in the figure; OAB responder rate at 24 months was 84% (95% CI: 79%-89%). At 24 months, UI subjects had a mean reduction from baseline of 2.3±2.9 leaks/day; UF subjects had a mean reduction of 5.2±4.6 voids/day (both p<0.0001). Subjects showed a statistically significant improvement from baseline to 24 months in all measures of ICIQ-OAB QOL instrument (Concern, Coping, Sleep, Social, Health Related Quality Life; all p<0.0001). The mean change from baseline to 24 months in total QOL score was 38.3±25.6). A reduction in the severity of depression (BDI-II) and pelvic pain (VAS) were demonstrated (both p<0.0001). Improvements in sexual function were found for female subjects (p<0.0001). Device-related adverse events occurred in 36% (99/272) of subjects through 24 months, with one event of implant site erosion being serious. The majority of adverse events were minor, the most common being an undesirable change in stimulation (15%).

Interpretation of results and concluding message:

These data show that SNM is safe and effective and improves the overall quality of life through 24 months of follow-up when offered to subjects with milder OAB symptoms, without requiring failure of all medications.



Disclosures

Funding: Medtronic **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov; InSite for Overactive Bladder, NCT00547378 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board of each participating institution or WIRB **Helsinki:** Yes **Informed Consent:** Yes