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LONG-TERM EFFICACY, SAFETY AND QUALITY OF LIFE RESULTS OF SACRAL NEUROMODULATION FOR THE TREATMENT OF VOIDING DYSFUNCTION'S: OUTCOMES FROM A PROSPECTIVE, WORLDWIDE CLINICAL STUDY

Hypothesis / aims of study

Sacral neuromodulation is established treatment modality for various types of voiding dysfunction. We report the results of a multicenter trial that was designed to evaluate long-term efficacy, safety and quality of life in patients with urge incontinence, retention and urgency-frequency that received Sacral Neuromodulation therapy.

Study design, materials and methods

Seventeen centers worldwide participated in this long-term study. 156 patients were implanted with InterStim system (Medtronic, Minneapolis). There were 20 males (12.8%) and 136 females (87,2%) and the mean age was 45.0 years ± 11.6 years (18.3 – 79.5).
97 patients (62.2%) had urge incontinence, 25 (16.0%) urgency/ frequency and 34 patients (21.8%) had idiopathic urinary retention. Voiding diaries were collected annually throughout five years. Success was considered as ≥50% improvement in primary voiding diary variables that were separately identified for each patient's group. Patients who exited the study for the lack of efficacy or adverse event were considered therapy failure and were included in the analysis.

Results

Five-year data was available from 93 patients. Data from the remaining patients were reported during the intervals from which they were available. Average number of leaking episodes/day for 53 urge incontinent patients went down from 10.2 $\pm$ 6.4 at baseline to 3.6 $\pm$ 4.0 after 5 years follow-up. For urgency-frequency patients, the average number of voids/day at baseline decreased from 19.0 ± 6.8 to 13.6 $\pm$ 7.1 (n=15) at 60 months. Average volume voided/void at baseline increased from 90.5 ± 50.7 ml to 215.6 ± 166.7ml at 60 months. Average catheterized volume/ catheterization for implanted retention patients decreased from 356.7 ± 172.5 ml to 68.3 $\pm$ 119.5 ml at 60 months. Important finding is that once a patient is successful after 12 months, there is a high likelihood of continued success up to 60 months: 85.7% for urge incontinence, 83.3% for urgency-frequency and 90.5% for urinary retention.
At 60 months follow up, 64.2% of the UI patients, 66.7% of the U/F and 76.0% of retention patients had successful outcomes.
SF-36 physical component scores showed significant improvements at 6 and 12 months for UI, 6-36 months for U/F, and 6, 12, 48, and 60 months for UR. SF-36 Mental component scores showed significant improvements at 6 through 36 months for UI and 6 through 36 months for U/F. Beck depression scores, which indicated mild to moderate baseline depression for UI and U/F patients, showed significant improvements at 6-48 months for UI and 6-36 months for U/F.
There were no severe or irreversible adverse events reported and 91.7% of the reported adverse events have been resolved at the time of database closure. Of 156 patients, 100 experienced 30 device-related and 236 therapy related adverse events. Overall, 14 patients were explanted due to an adverse event or lack of efficacy.

Concluding message

The results of this long-term study demonstrate that InterStim therapy is effective and safe for restoring voiding in patients who are refractory to other forms of treatment. 86.8% of the patients that were successful after one year were still successful after five years. It also shows that patients treated with sacral neuromodulation notice an significant improvement in their quality of life. Other proven advantages of neuromodulation are its reversibility and relative non-invasive nature when compared to surgical alternatives the physician can offer to the patients with refractory lower urinary tract symptoms.

SF-36 and Beck over time

UI

Score	Baseline	6 mos	12 mos	24 mos	36 mos	48 mos	60 mos
PCS	35.2	39.8*	40.1*	38.3	39.1	36.8	36.5
MCS	44.1	48.9*	49.9*	48.9*	49.0*	47.7	45.1
Beck	13.8	8.2*	8.1*	9.6*	8.5*	10.2*	11.8

U/F

Score	Baseline	6 mos	12 mos	24 mos	36 mos	48 mos	60 mos
PCS	35.0	44.9*	43.3*	45.8*	48.1*	48.0	45.2
MCS	43.0	53.0*	47.9*	52.6*	56.4*	49.8	54.2
Beck	11.5	6.8*	8.6	5.6*	2.5*	5.9	2.7

UR

Score	Baseline	6 mos	12 mos	24 mos	36 mos	48 mos	60 mos
PCS	36.6	42.0*	42.9*	38.0	40.9	42.1*	41.8*
MCS	50.8	51.5	50.4	52.8	50.8	51.3	46.3
Beck	7.6	6.1	8.5	6.5	7.2	6.2	8.6

* $p < 0.05$

FUNDING: Medtronic Europe SARL