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A PROSPECTIVE, RANDOMIZED, MULTI-CENTRE TRIAL EVALUATING EFFICACY, QUALITY OF LIFE AND SAFETY OF SACRAL NEUROMODULATION VS STANDARD MEDICAL TREATMENT IN SUBJECTS WITH SYMPTOMS OF OVERACTIVE BLADDER

Hypothesis / aims of study

The ICS currently recommends sacral neuromodulation (SNM) as a third line therapy for idiopathic overactive bladder (OAB). However, a direct contemporary comparison of the effectiveness of SNM to standard medical treatment (SMT) (second line therapy) has not been demonstrated. The InSite for OAB trial evaluated the 6 month success rate and changes in quality of life (QoL) of SNM with InterStim® therapy vs SMT for treatment of OAB.

Study design, materials and methods

This prospective, randomized, multicentre trial included patients with bothersome symptoms of idiopathic OAB including urinary urge incontinence (OAB wet) or urge frequency (OAB dry) who failed at least 1 anticholinergic medication and had at least one medication not yet attempted. This group represents a less severe segment of SNM eligible subjects than previously studied in a multicentre trial. Patients discontinued OAB medications prior to and during baseline assessment and were randomized 1:1 to SNM or SMT. Patients in the SNM arm underwent test stimulation and were implanted with SNM if successfully tested. Patients in the SMT arm restarted prior OAB medication or started the next recommended medication.

Results

Overall, 147 patients were enrolled and randomized to SMT (n=77) or SNM (n=70; n=51 implanted). Of these, 93% of subjects were female and the mean age was 58.7 years. Comparison of the primary and secondary outcome measures from baseline to 6-months between SNM and SMT are presented in table 1.

Table 1: Outcomes at 6 months as compared to baseline

	Therapeutic Success Rates[1] [%]		Quality of Life[§] - Changes in ICIQ-OABqol[2] from Baseline [mean ± SD]					
	ITT[†]	As treated[‡]	Concern	Coping	Sleep	Social	HRQL total	Interference
SNM	61.4%	76.5%	46.9 ± 29.1	44.5 ± 32.2	36.5 ± 28.5	27.2 ± 29.2	40.1 ± 26.5	-4.6 ± 3.0
n=	70	51	51	51	51	51	51	51
SMT	41.6%	49.3%	16.0 ± 23.6	14.3 ± 23.6	11.1 ± 22.0	9.0 ± 19.1	12.5 ± 18.8	-1.6 ± 2.5
n=	77	73	77	77	77	76	76	74
p-value	0.016	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

† Includes all subjects analysed per their randomized arm. Data for subjects discontinued prior to 6 months were set to baseline values.

‡ Includes subjects with diary data at baseline and 6 months (124/147); subjects were analysed according to the treatment they received.

§ Subjects that completed at least one QoL measure at baseline and 6-months were analysed with the treatment they actually received. Shown are mean values with standard deviations.

[1] Therapeutic success defined as a ≥ 50% reduction in the average number of leaks/day (OAB wet), or a ≥ 50% reduction in number of voids/day or a return to normal voiding frequency (< 8 voids/day) (OAB dry).

[2] QoL measured with the International Consultation on Incontinence Modular Questionnaire - Overactive Bladder Quality of Life (ICIQ-OQBqol) instrument.

Device-related adverse events (events with an etiology of programming/stimulation, implanted system, surgery/anesthesia, or incisional site/device tract) occurred in 23.7% (14/59) with a lead implant. None of these were serious. The most frequent (>2%) device-related adverse events were implant site pain (8.5%), lead migration/dislodgement (3.4%), and implant site infection (3.4%). There were no unanticipated adverse device effects. OAB medication-related events occurred in 26.0% (20/77) of SMT subjects. Statistical comparisons were made between the 51 SNM subjects with full system implant and 75 SMT subjects without an implant. There were no statistically significant differences between the groups in any adverse event category or for any serious adverse event.

Interpretation of results

The SNM group showed statistically significant improvements vs the SMT group in success rate and QoL and an acceptable safety profile as assessed through adverse event analysis.

Concluding message

These data from the InSite OAB trial suggest that SNM with Interstim® Therapy is more likely to result in therapeutic success and improvements in QoL than an additional trial of SMT among subjects who have not exhausted all medication options.

Disclosures

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