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EFFECTIVENESS OF SACRAL NERVE STIMULATION FOR FECAL INCONTINENCE IN PATIENTS WITH DOUBLE INCONTINENCE

Hypothesis / aims of study

Urinary incontinence is a debilitating condition with severe impact on quality of life. An even more devastating condition is the simultaneous existence of both urinary and fecal incontinence (FI), or “double incontinence.” Sacral nerve stimulation (SNS) has been approved for use in treating urinary incontinence in the U.S. since 1997. A large multicenter trial investigating the safety and efficacy of SNS for FI was recently completed, with results currently under FDA review. It is uncertain whether double incontinence could indicate a more severe pelvic floor disorder that might be more difficult to impact with SNS. The purpose of the current analysis was to investigate FI SNS therapy outcomes in those patients exhibiting double incontinence compared to patients with only FI.

Study design, materials and methods

Candidates for SNS who provided informed consent were enrolled in this IRB-approved multi-centered prospective trial. Patients showing ≥ 50% improvement in fecal incontinence during test stimulation received chronic implantation of the InterStim® (Medtronic; Minneapolis, MN) Therapy system. The primary efficacy objective was to demonstrate that ≥50% of subjects would achieve therapeutic success, defined as ≥50% reduction of fecal incontinent episodes per week at 12 months compared to baseline. Outcomes for those patients exhibiting double incontinence were compared to those with only fecal incontinence. The following results represent complete case analyses at 12-month follow up.

Results

120 (110 females) of a mean age of 60.5 years and a mean duration of FI of 6.8 years received chronic implantation. 39 patients (33%) reported double incontinence at baseline. Double incontinent patients were significantly older than those with FI (64.2 years vs. 58.7; $p<0.05$) but were similar in terms of gender, BMI, and years with FI. Groups did not differ in either type of FI (urge, passive, or other) or FI etiology (injury, obstetric trauma, post-surgical, other) at baseline. Both groups showed similar and significant reductions in fecal incontinent days per week at 12 months compared to baseline, with FI-only patients reporting a mean reduction of 7.6 FI episodes per week and double incontinent patients reporting a reduction of 6.7 episodes. Similar findings were shows in for incontinent days per week and urgent FI episodes per week. Success rates (≥50% reduction in the number of fecal incontinent episodes per week) were not significantly different between groups.

Interpretation of results

Patients in this trial with double incontinence were similar in demographics and FI symptom presentation to those patients reporting only FI. Furthermore, Therapeutic success for treatment of FI was similar for both groups. Sacral nerve stimulation with InterStim® Therapy significantly reduced the severity of FI from baseline to twelve months for FI-only and double incontinent patients.

Concluding message

Results of the current analysis suggest that double incontinence should not preclude consideration for SNS therapy for fecal incontinence.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinicaltrials.gov**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**A single ethics committee was not used in this study. This study was conducted under an Investigational Device Exemption (IDE) protocol that was approved and overseen by the US Food and Drug Administration (FDA). It was approved by each Institutional Review Board at participating sites.**
Was the Declaration of Helsinki followed?	**Yes**

Was informed consent obtained from the patients?	**Yes**