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SACRAL NEUROMODULATION TINED LEAD MIGRATION RATE AT 5 YEARS POST-IMPLANT

Hypothesis / aims of study

To evaluate the cumulative tined lead migration rate at 5 years after InterStim™ implant in subjects with overactive bladder (OAB).

Study design, materials and methods

InSite is a prospective, multicenter post-approval study. Subjects with bothersome symptoms of 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. Subjects completed test stimulation with an external neurostimulator and if successful went on to receive the full InterStim system implant. Implanted subjects were followed at 3 months, 6 months, 12 months, and then annually to 5 years post-implant. Therapeutic success was defined as a UI or UF response; for UI as a $\geq 50\%$ improvement in average leaks/day, for UF as a $\geq 50\%$ improvement in voids/day or a return to normal voiding frequency (<8 voids/day) on a 3-day consecutive voiding diary. Adverse events including lead migration/dislodgment were collected at scheduled and unscheduled visits. Suspected tined lead migrations resulting in an adverse event of lead migration/dislodgment were included in the analysis. Months from implant of the full system to first adverse event of lead migration after full system implant in each subject was the outcome metric, regardless of when the subject was implanted during the trial. Subjects that were lost-to-follow-up or did not experience this event prior to the end of their follow-up were treated as censored observations. Results are reported as a Kaplan-Meier estimate of the survival function at five years. Study approval was given by institutional review boards and all subjects provided informed consent.

Results

Of the 340 subjects who went through test stimulation, 272 were implanted. For subjects implanted with the full system, 91% were female and mean age was 57 years. At 5-years, the lead migration adverse event rate was 5.9% (95% CI: 2.9% - 8.9%). A total of 17 lead migration adverse events occurred in 14 subjects on or after neurostimulator implant. Specifically, on or after neurostimulator implant 11 subjects experienced 1 adverse event of lead migration which corresponds to 11 adverse events and 3 subjects experienced 2 such adverse events which correspond to 6 adverse events. Reprogramming was initially attempted in nine events. Eventually all leads were replaced. All events were resolved without sequelae.

Interpretation of results

A 5-year tined lead migration adverse rate of 5.9% is low. This rate is improved from the original InterStim post-approval study which indicated a lead migration adverse event rate of 9.3% at 5 years.

Concluding message

Improvements have been made in the tined lead design and related implant technique since the original InterStim post-approval study. In this current large, multicenter study a low and acceptable lead migration adverse event rate has been demonstrated.

Disclosures

Funding: This clinical study was sponsored by Medtronic **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov, NCT00547378 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board, Western Institutional Review Board **Helsinki:** Yes **Informed Consent:** Yes