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DELAYED LEAD MIGRATION AFTER PLACEMENT OF SACRAL NEUROMODULATORS – DO OUTCOMES PARALLEL THE EXTENT OF LEAD MOVEMENT?

Hypothesis / aims of study

Since the approval of Interstim sacral neuromodulation (SN) in 1997, patients with refractory urge urinary incontinence, increased daytime frequency and urgency, and nonobstructive chronic retention of urine have benefited from a significant reduction of symptoms. Over time however, there appears to be a slow, but progressive loss of efficacy of SN. This loss of efficacy may be related to several factors, including impedance problems with the circuitry and generator failure. In early trials, lead migration was also responsible for poor success over time. The tined lead was developed to simplify placement of the stimulation lead, and minimize the risk of migration. There have been no reports studying long-term risk of migration and any possible relation of tined lead migration to efficacy of SN. Our aim with this study was to investigate the incidence and extent of radiographically-determined tined lead migration. Furthermore, we examined correlations between lead migration and change in symptoms/efficacy of SN.

Study design, materials and methods

Following IRB approval, all patients who underwent SN placement (stage I and II) from January 2006 to June 2008 at our institution were identified. Medical records were retrospectively evaluated for history, operative intervention and follow up visits. All patients with satisfactory test stimulation and advancement to permanent lead placement with over 6 months follow up were asked to return for a single lateral XRAY of the sacrum. PGI-I and UDI-6 questionnaires, as well as a visual analog scale QOL assessment were completed by each subject. A blinded radiologist recorded lead position from intraoperative XRAYs taken at initial lead placement and those taken at follow up. Lead migration was evaluated by measuring the distance from the S3 foramen to the lead tip, as well as any change in angulation of the lead tip. Lead migration and patient questionnaire data were analyzed for any correlations.

Results

A total of 33 patients underwent stage II SN placement. Three patients underwent device removal due to pain at the generator site, abnormal impedance measurements, or loss of efficacy of no known etiology. One patient moved out of the country, and one is deceased due to an unrelated cause. To date, 6 patients have returned for follow up films. Median patient age was 69.5 yrs (range 53-81). All were women. Indications for SN included refractory urge urinary incontinence in 5 patients, and pelvic pain in one patient. Median follow up was 16.5 months. No abnormal impedance measurements were noted. Radiographic measurements revealed migration of the lead inward, toward the presacral space, in 4 patients. Two patients had no lead movement at all. Median lead migration was 10 mm (range 2 -- 11 mm). Using the cut-off BMI ≥ 30 for obesity (n=2), there was no correlation between obesity and lead migration. Angulation of the lead tip was measured as positive (increased angulation toward the sacrum), or negative (angulation away from lower edge of sacrum). Change in angulation ranged from -15.7 to + 19.9. PGI-I scores varied, with one patient reporting “a little better”, 3 patients reporting “much better”, and 2 patients reporting “no change” in symptoms since placement of SN. Patients reporting an improvement in symptoms (“a little better” or “much better”) were more likely to have lower overall UDI-6 scores (p=0.0391), and lower scores on UDI question 2 (urge UI) (p=0.0154). There was no association between PGI-I or UDI-6 scores and lead movement (p=0.82), or lead tip angulation (p=0.076). QOL scores were not significantly different between the groups.

Interpretation of results

On median follow up of 16.5 months, only minor inward lead migration was observed of the SN tined stimulation lead. In all cases but one, movement was inward, toward the presacral space. Patients reporting improvement on the PGI-I were also noted to have overall improved UDI-6 and UDI question 2 (urge UI) scores. However, there was no difference in the degree of lead migration from patients reporting improvement to those with no improvement. The finding that QOL scores were not different between the improvement vs. no improvement groups suggests that QOL assessment is multifactorial, depending not only on symptom improvement, but other factors including patient expectations.

Concluding message

When patients report a decline in efficacy of SN over time, various algorithms exist for determining an etiology before intervention. In the absence of other complications such as infection or pain at the generator site, suspected etiologies of poor efficacy include abnormal impedance, generator malfunction, and lead migration. The findings of this study demonstrate that minimal lead migration occurs, yet the degree of migration is unrelated to SN efficacy. Furthermore, these data suggest that a progressive decline in symptom relief over time may have to do with neurophysiologic adaptations in response to SN, and less to do with the device itself.

Specify source of funding or grant	**None.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The University of Texas Southwestern Medical Center at Dallas Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**