PD36-03

12 YEAR SINGLE CENTER RETROSPECTIVE REVIEW OF RISK FACTORS AND RATE OF TINED LEAD BREAKAGE DURING SACRAL NEUROMODULATION LEAD EXPLANT

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INTRODUCTION AND OBJECTIVES: The tined lead for use with InterStim sacral neuromodulation (SNM) was introduced in 2002. However, little data on lead breakage has been published. In 2010 the manufacturer estimated a 1% rate of lead breakage and recommended removal from an incision over the sacrum (as opposed to from generator site). We previously described 5-year data of an 18% rate of lead breakage with risk factors of time since implantation and diabetes. The purpose of this review was to extend this data, and further define rate and risk factors for lead breakage.

METHODS: We retrospectively reviewed lead explants from 2006 to 2018. Patients with non-tined lead, missing information or explant for infection or failed stage 1 were excluded. Clinical factors reviewed included age, BMI, gender, diabetes, time since implantation, history of prior revision and explant indication. Surgical techniques reviewed included cannulating the old lead with a straight stylet, and removal from an incision over the sacrum vs the generator site. Statistical analyses were performed as appropriate.

RESULTS: 283 patients met study eligibility requirements. Patients were predominantly female (93%), non diabetic (85%), with mean age of 53 $\pm$16, mean BMI 29.3$\pm$7.8, and mean time since implantation of 2.8 $\pm$2.1 years. Rate of lead breakage was 8.1%. The only significant difference between lead intact to lead breakage groups was time since implantation ($p<0.001$). On univariate analysis the following clinical factors were predictive of lead breakage: male gender, diabetes, time since implantation, history of fall/trauma, and surgeon. On multivariate, only gender (OR 8.2 95% CI 2.6-25.5) and time since implantation (OR 0.675 95% CI 0.555-0.821) remained significant. There was a 67% increased risk of lead breakage if time since implant was 4.5 versuss 2.2 years and an 8.2 times higher risk of lead breakage in males. Surgical technique used for lead removal was not significant.

CONCLUSIONS: Overall rate of lead breakage was higher than estimated by the manufacturer, with the strongest predictor of lead breakage being the time interval since implantation. Interestingly, in all cases of lead breakage an incision over the sacrum had been made and this was not a protective factor. These findings are valuable for patient counseling prior to SNM revision.

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PD36-04

IMPROVING PATIENT EXPERIENCE WITH SACRAL NEUROMODULATION: A HUMAN FACTORS APPROACH

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INTRODUCTION AND OBJECTIVES: Sacral neuromodulation (SNM), though minimally invasive, involves an initial testing phase that requires active patient participation. These steps are complex and, if a patient does not receive adequate pre-procedure education, can be difficult to conceptualize. Pre-procedure preparedness has been found to impact post-procedure satisfaction and perceived treatment outcomes. The goal of this study was to conduct a needs assessment of patient preparedness, education, device usability and satisfaction regarding all stages of sacral neuromodulation therapy. Using a human factors approach, we conducted a needs analysis to identify opportunities for improvement in the efficiency and quality of care delivery.

METHODS: Candidates for SNM (as determined by one of three FPMRS specialists) were recruited to participate before undergoing staged SNM. Ten patients were observed and their experiences were evaluated at four phases: 1) Date of test implant (Stage I); 2) 5 days following the test implant procedure; 3) date of permanent implant (Stage 2); 4) 3 months following the permanent implant procedure. Questionnaires administered to patients throughout this process included a preoperative preparedness questionnaire, a post-operative satisfaction/usability survey (close-ended questions), and a post-operative satisfaction/usability survey (open-ended questions).

RESULTS: With respect to pre-operative preparedness, patients generally did not understand the risks of the planned procedures, did not know what to expect postoperatively, and were not satisfied with preoperative materials. Patients were confused on how to adjust the settings for both the test and permanent implant devices. When asked if they would choose the same treatment again and if they would recommend this treatment to a friend/family member, 30% indicated they would not. Every patient reported that their symptoms were at least “a little better” postoperatively. The overall systems usability scale score of the test device was a 55.6 across all patients (a score of 68 is considered average for usability), while the score for the permanent device was a 50.0; both scores are considered “below average” for usability.

CONCLUSIONS: This pilot needs analysis demonstrates that there are several opportunities for improvement for patients undergoing sacral neuromodulation. These findings highlight the opportunities for a mutli-faceted intervention, including the development of an informational sheet/video, an in-service training for all PACU nurses, and updated discharge instructions.

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PD36-05

EXAMINING SUCCESSFUL TREATMENT WITH SELECTIVE BLADDER DENERVATION (SBD) AFTER 18-MONTHS: HABIT-DRIVEN VERSUS URGENCY-DRIVEN VOIDING IN REFRACTORY OAB PATIENTS

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