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SACRAL NEUROMODULATION: LONG-TERM EFFICACY, INCIDENCE AND PREDICTORS OF COMPLICATIONS

Hypothesis / aims of study
The aim of this paper is to examine the long-term efficacy and durability of sacral nerve stimulation (SNS), report the complications in a large series of patients and to identify predictors of complications / failures in order to optimize patient selection and outcomes.

Study design, materials and methods
A retrospective review was performed to determ the incidence and predictors of complications with SNS. Patients with refractory urgency incontinence, urgency/frequency or idiopathic urinary retention treated with SNS were identified and selected as the study cohort. Patients completed a one-week voiding log and underwent urodynamic evaluation prior to staged SNS lead placement with the Interstim® (Medtronic) device. Patients were followed for evidence of complications and device efficacy. Patients and device variables including operative indications, patients co-morbidities and social history, as well as the type of lead and generator employed were examined statistically for evidence of predictive value.

Results
From June 2001 to March 2008 271 patients (228 females and 43 males) with an average age of 52 years (range 17-86 years underwent staged SNS lead placement by a single surgeon, for intractable urgency incontinence (126), urgency/frequency (105) or idiopathic urinary retention (40). Of this group 244 patients (90%) experienced a greater than 50% improvement in symptoms based on a one-week voiding log and underwent IPG placement. At mean follow-up of 38 months (range 2-80 months) complications were identified in 62 patients (25%). 45 patients (18%) required either lead revision, IPG revision or both secondary to lead migration or trauma; 3 patients (1%) developed haematoma at the IPG site requiring explanation or drainage; and a total of 39 patients (16%) have had their device explanted. Of these 13 (5%) were for infections, 5 (2%) were because the patient required an MRI exam, 1 was for intractable diarrhea and 20 (8%) were for lack of durable efficacy or because the patient wanted it removed. When analyzed statistically patient who were wheelchair bound had a body mass index (BMI) <18 or >30, and/or had a past history of recurrent trauma were significantly more likely to experience device complications or failures ($p < 0.5$). There was a trend towards revisions and complications among public aid recipients and patients treated in a pain clinic ($p = 0.071, 0.063$). Use of a non-tined lead was a predictor for device revision ($p <0.05$). Likewise complications and revision rates for the IPG II were rare. Overall, 207 patients (85%) presently have functioning Interstim ® device.

Interpretation of results
SNS is an effective treatment for patients with intractable voiding dysfunction. Complications are not uncommon but can be minimized.

Concluding message
Complications may be minimized with better patient selection, use of the IPG II, an experienced surgeon and a dedicated clinical programmer. A committed and educated patient may ultimately represent the most important key to success.

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?	**No**
This study did not require eithics committee approval because	**this is a retrospective review of patients treated with SNS for their voiding dysfunction**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**