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COMPLICATIONS OF SACRAL NEUROMODULATION

Aims of Study

Sacral Neuromodulation (InterStim, Medtronic Inc.) is approved for voiding dysfunction. The technique for testing response and implanting the unit has undergone many procedural changes. Traditionally, the reoperation rate has been reported to be 35% to 40% and explantation up to 11%. With the advent of the "stage" technique under sedation with a minimally invasive approach to placing the permanent quadripolar lead, our objective was to determine the contemporary complication, reoperation and explantation rate.

<u>Methods</u>

A retrospective chart review was performed on all patients undergoing a permanent sacral nerve implant for voiding dysfunction after responding to a two week test period. The complication, reoperation, and explantation rate was determined. Also, reasons for reoperation were assessed along with final outcomes.

Results

From 5/00 to 10/02, 60 permanent implants by a single surgeon were performed, with a mean follow-up of 295 days. Reasons for implant included 50 for interstitial cystitis (83%) and 10 for urgency/urge incontinence (17%). The staged technique, placing the permanent quadripolar lead for the test period, resulted in an 83% test to implant rate. Early complications included sterile wound seroma in 2 patients requiring needle drainage. Reoperation occurred in 9/60 (15%) with a mean time from implant to reoperation of 216 days. Two of nine (22%) required more than one reoperation for the same problem. Reasons for reoperation included: 1 lead migration, 2 lower extremity (S2) motor response, 2 sensory discomfort, 3 implantable programmable generator (IPG) pocket revisions, 1 IPG failure. The lead migration occurred from bending and lifting a heavy object several weeks after the implant. No reoperation for sensory discomfort occurred after placing the lead under sedation and assessing sensory response. Two of the IPG pocket revisions were from the connector being anterior to the IPG causing pain and pending erosion. The IPG failure occurred spontaneously with the unit resetting itself to factory standards. An explant occurred in 1 patient (1.7%) for an infected IPG site (Serratia marcescens) occurring 99 days after 2nd revision for sensory discomfort. No life-threatening or irreversible complications occurred.

Conclusions

Overall 15% of patients underwent reoperation and one patient (1.7%) required explantation. Reoperation may be decreased at the time of implant by assessing sensory response during lead placement, placing the connector below the IPG, and confirming S3 placement by always finding and stimulating S2. Sacral nerve stimulation is effective for treating voiding dysfunction and has an acceptable complication and reoperation rate. No serious, irreversible complications occurred.