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CONDITION SPECIFIC QUALITY INDICATORS FOR INTERSTIM NEUROMODULATION THERAPY

Hypothesis / aims of study

Sacral nerve stimulation (SNS) has been approved as a treatment for persistent lower urinary tract dysfunctions when other more conservative measures fail. Many studies have reported on the outcome of SNS using various objective and subjective measures, however, few have reported on the outcome in relation to specific preoperative indicators. The purpose of this study is to investigate the relationship between specific preoperative predictive variables (including patient age, sex, and specific diagnosis) and certain outcome variables after interstim therapy (including implantation rate, revision rate, explantation rate, infection rate, and number of programming visits).

Study design, materials and methodsWe retrospectively reviewed a prospective database of 196 patients who had failed conservative therapy and underwent neuromodulation therapy using the interstim staged implantation technique for a variety of lower urinary tract dysfunctions. All patients underwent evaluation using PNE or staged procedure. Stage II was performed for a 50% or more improvement in symptomatology. Preoperative predictive values as well as postoperative outcome variables were collected and entered into computer system.

Results

Our study included 196 patients (167 women and 29 men) with mean age of 50.7 years. Mean follow-up period was 18 months. In 46 patients (23.5%) revision for the Stage I electrode was done. Reasons for revision in those patients were as follow: lack of the desired clinical response in 36 patients, device malfunction in 7 patients, and infection in 3 patients. In those patients who underwent revision for stage I: 16 / 46 (34.8%) eventually went to stage II while in 30 / 46 patients (62.2%) the neuroelectrode was explanted due to lack of the efficacy. Of the all 196 patients who had initial screening, 132 / 196 patients (67.3%) went to stage II. There were13 cases of wound infection (6 cases in stage I and 7 in stage II) The mean number of programming visits was 2.6 and there was no significant difference in the number of programming visits among different diagnoses. The interstim therapy has lost its efficacy in 21 of the 132 patients who underwent stage II (16.6%) over an average follow-up of 14. In 13 / 21 patients the device was explanted, in 2 / 21 patients the device was left but turned off, while in 6 patients the device was left turned on.

Interpretation of results

We noted suboptimal results from Stage I revisions that were revised due to lack of the clinical response. The rate of revisions / explantations for Stage I or Stage II was not related to specific indications / conditions. No significant difference in the number of programming visits required for a specific indication was noted.

Concluding message

- Overall, success with Interstim neuromodulation is quite high.
- Implantation rate after staged technique is better than after that after the PNE, and it is recommended for initial screening.
- We recommend revision of stage I for those patients who did not show improvement
 after the initial screening especially if the later has been performed by PNE, however,
 the physician should be aware that success rates will not be as high as the initial
 screening stage I.
- The rate of revisions / explantations for Stage Stage II or I is not related to specific preoperative indication or condition.