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SACRAL NEUROMODULATION REDUCES NARCOTIC REQUIREMENTS IN REFRACTORY INTERSTITIAL CYSTITIS

Aims of Study

Interstitial cystitis (IC) is a symptom complex of urinary urgency, frequency, and pelvic pain often necessitating narcotics. In addition, many IC patients complain of urinary hesitancy, intermittency, irritable bowel symptoms, and vaginal pain. Some patients with IC will respond to multimodality therapy including behavioral and pharmacological treatments. Unfortunately, a subset of IC patients with pelvic pain continues to suffer from their disease despite trying all standard therapies. This may arise from a neurogenic component of IC in which chronic stimulation results in a pathologic upregulation of pelvic nerves with subsequent pelvic muscle dysfunction. As a result, it is logical to investigate neuromodulation as a means to treat not only urgency/frequency of IC, but also the pelvic pain component.

The purpose of our study was to assess the efficacy of long-term sacral neuromodulation in treating chronic pelvic pain associated with interstitial cystitis refractory to standard therapy. Objective endpoints included morphine IM dose equivalents determined pre- and post-implantation. Subjective data was evaluated using a standard seven-point scale.

<u>Methods</u>

Patients who demonstrated the symptom complex of urinary urgency, frequency, and pelvic pain and had failed an average of six prior traditional IC treatment modalities were defined as refractory IC patients for the purpose of this study. All patients had undergone cystoscopy and hydrodistension prior to InterStim® implantation. All had glomerulations, with 19% demonstrating Hunner's ulcers, and mean anesthetic bladder capacity was 740 cc. Patients elected sacral nerve modulation for the urgency and frequency aspect of their disease. Pain was monitored as a secondary variable. Patients underwent permanent implantation of the sacral neuromodulation device after responding to a temporary test. All InterStim® devices were implanted by a single surgeon between May 2000 and February 2002 and only patients with a minimum follow-up of 6 months from implantation were included in this study.

Baseline narcotic use was determined by chart review, and post-operative pain scores and narcotic use were collected with questionnaires. Narcotic requirements prior to and following sacral neuromodulation were standardized to intramuscular morphine dose equivalents using Mosby's Drug Consult, 2002 (MD Consult Drug Text online). Statistical analysis was generated by the paired t-test and supported by the Wilcoxon sign paired test (non-parametric). Significance was predetermined at p<0.05.

Results

A total of 21 consecutive IC patients who had chronic pelvic pain and were refractory to standard therapies underwent InterStim® implantation. The mean age was 45.5 years (range 17-68) with 81% female and 19% male. Questionnaires were sent to all identified patients who had a permanent implantation and 100% of questionnaires were returned. The mean follow-up after implantation was 15.4 months (range 7.4-23.1).

Eighteen of 21 (86%) used chronic narcotics prior to InterStim®, with the remaining three patients using non-narcotic analgesics. Narcotic users averaged 81.6 mg/day MDE prior to implantation. Following sacral neuromodulation MDE requirements decreased to an average of 53.0 mg/day (35%), (p-value =0.015). Four of 18 patients (22%) ceased all narcotics after InterStim® permanent implantation.

Patients were asked to rate their pelvic pain associated with interstitial cystitis following sacral neuromodulation as *markedly worse, moderately worse, slightly worse, the same, slightly improved, moderately improved, or markedly improved.* Twenty of 21 patients (95%) reported moderate or marked improvement in pain following InterStim®. The remaining patient reported no change in her pelvic pain.

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Conclusions

Sacral neuromodulation decreases narcotic requirements and subjective pelvic pain in refractory interstitial cystitis patients. Further decreases in MDE are anticipated as dose reduction in improved patients continues.