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PELVIC FLOOR ELECTROSTIMULATION FOR THE TREATMENT OF INTERSTITIAL CYSTITIS

Aims of Study

Interstitial Cystitis (IC) is a chronic and severely debilitating syndrome characterized by pelvic pain, often accompanied by sensory irritative voiding symptoms. A prospective evaluation of implantable pelvic floor electrostimulation was performed to assess efficacy in severe refractory Interstitial Cystitis using the miniaturTM-I system (BioControl Medical, Israel).

Methods

Eight patients, mean age of 57 (range 43-72 yrs.), with symptoms and cystoscopic findings compatible with National Institute of Arthritis, Diabetes and Digestive and Kidney Disease (NIDDK) criteria for IC underwent pelvic floor electrostimulation. All patients enrolled in the study had suffered from severe Interstitial Cystitis symptoms for years and had failed more conservative treatments. Greater than 30% improvement in baseline pain and voiding symptoms during a temporary 6-7 hours of miniaturTM-I electrostimulation test system (MTS-I) use, qualified a patient for permanent implantation of the system. The miniaturTM-I system consists of an implantable, pacemaker-like, electrostimulator placed subcutaneously in the anterior abdominal wall and a bipolar stimulation lead implanted adjacent to the urethral midpoint via a minimal invasive procedure.

Patients were evaluated using pain scores, urinary diary variables and quality of life questionnaires at baseline, during test stimulation, and at 1,3,6 and 12 months after implantation.

Results

All eight patients had positive response to the MTS-I test stimulation and underwent permanent implantation of the miniaturTM-I system. The results were favorable; a substantial decrease in pain and frequency of urination per day was observed in all patients. Patients had been observed at one (8 pts.), 3 (5 pts.), 6 (3 pts.) and 9 months (2 pts.) post implantation. Mean pain on a scale of 1 to 10 was significantly decreased in all eight patients from 4.9+/-1.5 at baseline to 1.7+/-2.0 at one-month post implantation ($p < 0.05$); frequency of urination was also improved from 37.0+/-20.5 to 20.5+/-18.8 ($p < 0.05$). At 3 months, 5 patients showed significant improvement (decrease in symptoms) both in pain and frequency symptoms: 4.5+/-1.3 to 0.5+/-0.7 and 37.0+/-23.0 to 13.5+/-6.0, respectively. After six months of treatment, patients were pain free and frequency of urination decreased from 44.8+/-27.6 to 8.8+/-2.8. At nine months post operation, patients remained pain free and their frequency of urination further improved (from 43.5+/-38.9 to 8.3+/-3.3).

Positive impact of therapy effectiveness throughout the study was demonstrated in various aspects of quality of life using the O'Leary-Sant symptom and problem indices.

Conclusions

Interstitial Cystitis patients response favorably to the miniaturTM-I treatment with significant improvement in pelvic pain, daytime frequency and nocturia.