

CHRONIC PELVIC FLOOR ELECTROSTIMULATION FOR TREATMENT OF REFRACTORY INTERSTITIAL CYSTITIS

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INTRODUCTION & OBJECTIVES: Electrostimulation has been used extensively and successfully for the treatment of urinary dysfunction. In this study we present the effect of pelvic floor electrostimulation using the BioControl miniaturio™-I system as a novel treatment option for refractory Interstitial Cystitis (IC).

IC is a chronic syndrome characterized by a constellation of lower urinary tract irritative symptoms and pain. Clinically, IC is diagnosed on the basis of its major symptoms, i.e., urinary frequency, urgency and/or pelvic pain in the absence of any identifiable cause, such as bacterial infection or tumor. The etiology of IC is unknown, but may involve microbiologic, immunologic, mucosal, neurogenic, or other as yet unidentified factors.

MATERIAL & METHODS: Ten female patients, mean age 54 years old (range: 39-72 years), were recruited for the miniaturio™-I for Interstitial Cystitis study in two centers and completed a mean follow up period of 10 months (range: 3 to 18 months). Patients underwent a simple surgical procedure (under epidural or local anesthesia). Stimulation treatment was performed using a bipolar stimulation electrode placed adjacent to the mid-urethra and connected to a pacemaker-like electrostimulator located subcutaneously in the anterior abdominal wall. Efficacy was measured by comparing the results of the pre- and post-treatment voiding and pain diary and quality of life questionnaires.

RESULTS: Eight out of the 10 patients demonstrated sustained improvement in all three measured parameters, urinary frequency, pain and quality of life, at the last post-operative visit. At 10 months, the patients' frequency of micturition was considerably decreased, per voiding diaries, from an average 32.4 ± 20.6 per day down to 14.7 ± 10.0 ($p=0.01$). In parallel, their pain (on a visual analogue scale of 1 to 10) was significantly decreased from 4.6 ± 1.7 down to 1.0 ± 1.6 ($p=0.001$). Concomitantly, a significant decrease was observed in the O'Leary-Sant Symptoms and Problem Index scores (from 31.6 ± 3.4 down to 15.4 ± 13.5 ($p=0.001$)).

Five post implant surgical procedures were performed to resolve adverse events. Eight of the patients were satisfied with the results of the surgery and continue the treatment. Two patients who were not satisfied withdrew their consent to participate in the study and subsequently had their system removed 6 and 9 months after implantation.

CONCLUSIONS: In that cohort of patients, this form of electrostimulation therapy has been demonstrated to be effective and well tolerated for the treatment of refractory IC. Longer follow-up period is required to establish the efficacy of this method.