

## **INITIAL RESULTS OF PELVIC FLOOR ELECTROSTIMULATION FOR SYMPTOM RELIEF IN INTERSTITIAL CYSTITIS USING THE MINIATURO™-I SYSTEM**

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**INTRODUCTION & OBJECTIVES:** Interstitial Cystitis (IC) is a disabling chronic condition of the lower urinary tract. The etiology is not known. The treatment of IC is mainly empirical and includes multimodal behavioural therapy, pharmacological treatment, bladder instillations, and bladder hydro-distension. However, all treatments provide only temporary relief from the IC symptoms. The purpose of our study has been to assess the efficacy of chronic pelvic floor stimulation using a novel active implantable system on IC symptoms.

**MATERIAL & METHODS:** Adult women patients with diagnosed IC for more than 12 months and who have failed to achieve adequate improvement through conservative management are eligible for the study. After passing a 6-24 hours of stimulation test, patients undergo a simple surgical procedure during which the system is implanted. The pulse generator is implanted through a 4-5 cm suprapubic incision and stitched to the fascia. The bipolar stimulation lead is inserted paraurethrally and connected subcutaneously to the pulse generator. The system delivers intermittent pulses through the lead to the pelvic floor with the intensity determined according to patient sensations. Treatment success was measured by pain and voiding diary and response to quality of life questionnaires (QoL) including "O'Leary-Sant symptoms and problem Indices" (O'Leary-Sant Indices), "Short-form McGill Pain Questionnaire" (SF-MPQ) and "Pelvic pain and Urgency/Frequency patient symptoms scale" (PUF) at 1, 3, 6 and 12 months following implantation.

**RESULTS:** So far, 13 patients have enrolled in this study. Two out of the thirteen patients enrolled (15%) were excluded from the study, because they failed the initial test stimulation; and three patients withdrew due to personal reasons. Out of the eleven active patients, ten patients had completed one to nine months of follow-up post implantation and were statistically evaluated on an intention to treat basis. Ten patients demonstrated substantially decreased in pain level either measured by VAS (on scale from 1 to 10) or by Short Form McGill Pain Questionnaire: from 6.6+/-1.5 and 36.5+/-8.2 at baseline to 3.3+/-1.9 to 18.5+/-8.0 after treatment ( $p<0.01$  for both parameters), respectively. O'Leary-Sant Indices score reduced from 32.5+/-4.0 to 25.9+/-6.7 ( $p<0.01$ ). An additional quality of life tool, the Pelvic Pain and Urgency/Frequency scale (PUF), kept the same trend as the score reduced significantly from 26.5+/-3.7 to 19.9+/-3.5 ( $p<0.01$ ). The mean urinary frequency also decreased by 11% but the change is insignificant.

**CONCLUSIONS:** Pelvic floor electro stimulation has a positive effect on IC symptoms. Larger number of patients and longer follow-up are still required in order to establish this mode of treatment as a viable alternative for treatment of intractable IC.