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INTERSTITIAL CYSTITIS AND PELVIC FLOOR NEUROMUSCULAR STIMULATION

Hypothesis / aims of study
Interstitial cystitis (IC) is an extremely painful condition that results in recurring discomfort or pain in the bladder and the surrounding pelvic region. The exact causes of interstitial cystitis are unknown, and thus most treatments are aimed at relieving pain symptoms. We conducted an international trial to evaluate the preliminary efficacy of pelvic floor neuromuscular stimulation on IC patients.

Study design, materials and methods
Sixty-three patients, mean age 54 years (range: 21-80), responded positively to a test stimulation after having failed other therapeutic approaches. The responders were subsequently implanted with the System during a simple surgical procedure. The pulse generator was implanted through a 4-5 cm suprapubic incision and stitched to the fascia. The bipolar stimulation lead was 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. Study duration was one year and clinical outcome was determined by improvement in IC symptoms, i.e., pain relief per Visual Analogue Scale (VAS) from the Short Form - McGill Pain Questionnaire (SF-MPQ), decrease of voiding frequency and improvement in the O'Leary-Sant Symptom and Problem Index (O'Leary-Sant) as compared to baseline. The changes were statistically evaluated using a one-tailed Student's *t* test. Unadjusted P-values are reported.

Results
Fifteen out of the 78 patients enrolled (19.2%) were excluded from the study, because they failed the initial test stimulation; and 14 patients withdrew due to lack of efficacy (ten patients) and personal reasons (four patients). Out of the active patients, 43 patients had completed one year of follow-up post implantation and were statistically evaluated. Out of six patients who were not included in this abstract, five patients were lost to follow-up and one didn't reach the 12-month evaluation point.

Forty-three patients demonstrated substantially decreased pain level, either measured by VAS per SF-MPQ, from 7.3±2.1 at baseline to 3.8±2.8 after treatment ($p<0.01$), or O'Leary-Sant Indices, score reduced from 30.8±4.1 to 17.7±11.6 ($p<0.01$). The mean urinary frequency also decreased by 27.5%, from 23.5±15.9 times per day before the treatment to 17.1±15.3 times per day after 12 months of neuromuscular stimulation ($p=0.03$).

Interpretation of results
When we analyzed O'Leary-Sant results according to the respective domains, the decrease in the O'Leary-Sant Symptom and O'Leary-Sant Problem was significant as was the total score. The O'Leary-Sant Symptom and Problem score was reduced by 40.5% and 45.4%, from 16.8±26 and 14.0±1.8 at baseline to 10±6.3 and 7.6±5.4 at 12 months follow-up, respectively, demonstrating the remarkably positive effect on IC patients' quality of life following pelvic floor neuromuscular stimulation

Concluding message
Pelvic floor neuromuscular stimulation has a positive effect on IC symptoms. A 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.

References

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