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THE LONG TERM EFFECT OF ELECTROSTIMULATION OF THE PELVIC FLOOR ON PAINFUL BLADDER SYNDROME/INTERSTITIAL CYSTITIS PATIENTS

Hypothesis / aims of study
The aim of this abstract is to report long term effect of intermittent neuromuscular pelvic floor stimulation using the Accessa™ System (also know as miniaturo™-I) on patients who are suffering from Painful Bladder Syndrome/Interstitial Cystitis (PBS/IC)

Study design, materials and methods
PBS/IC is a chronic, inflammatory condition of the bladder and pelvic region with the predominate symptom of pain upon bladder filling and urine storage.
Neuromuscular stimulation for the treatment PBS/IC involves the application of electrical stimulation to the pelvic floor via an implantable system which consists of a bi-polar stimulation lead placed close to the external urinary sphincter and connected to an implantable pulse generator that is implanted in the lower abdominal region.
This study was approved by multinational ethics committees and involved 63 implanted subjects who had responded positively to an external stimulation test.
Efficacy was measured by comparing the results of the pre- and post-treatment voiding and pain diary, and via validated quality of life (QOL) questionnaires designed to assess QOL in PBS/IC patients. Intra-patient changes from baseline to follow-up were statistically evaluated using a two-tail student's *t* test. A p-value of less than 0.05 was considered statistically significant.

Results
At 18 months of stimulation treatment data is available for 19/63 patients with a mean age of 52 (range: 39-68 years). All 63 patients have either passed their 18 month follow-up or are no longer part of the study (20 withdrew after initial 12 month consent period, 4 were lost to follow-up, 20 underwent system removal for various reasons). The 19 subjects we report on, demonstrated improvement in all parameters. Pain per Visual Analogue Scale (VAS, 0- no pain to 10- severe pain) decreased significantly from 6.0±1.6 at baseline to 1.8±2.3 at the 18 month follow up visit ($p<0.0001$). Frequency decreased almost by half from an average of 22.4±14.7 voids per day to 11.1±5.9 voids per day ($p<0.01$). A decrease was also observed in the O'Leary-Sant IC Problems and Symptoms Indices score from 29.7±4.4 to 10.7±11.6 ($p<0.0001$) with a lower score indicating improved QOL.
Subjects were asked to grade their overall perception of the system on a scale of 0 to 3 (0 being most positive and 3 being least positive) by answering two global questions: 1) How much were their symptoms improved during treatment and 2) what was their overall satisfaction with the therapy?. Fifteen of the 18 subjects (83%) who answered these questions reported their symptoms were significantly improved and they were satisfied with the system after 18 months of treatment. Two subjects (11%) reported their symptoms were moderately improved and they were moderately satisfied with treatment, and one patient reported her symptoms worsened and satisfaction was low.

Interpretation of results
Close examination of the data revealed strong relationship between subjects overall perception of improvement and changes in pain level as reported in the pain diary, e.g. the patient who reported worsened symptoms and low satisfaction from the treatment had her pain level per VAS remain the same at 18 months FU as compared to baseline; the two subjects who reported moderate improvement in IC symptoms, had in 1 case an improvement in pain level per VAS of 21% and in the other case an improvement of 98%, while urinary frequency decreased by 23% and 26%, respectively. 9 of the remaining 15 subjects who reported significant improvement in their symptoms were pain free, and the other 9 experienced more than a 50% reduction in pain, while changes in urinary frequency varied within the group.

Concluding message
The results of this study suggest that intermittent pelvic floor electrostimulation may be beneficial in treating intractable PBS/IC patients long term. A larger number of patients will be needed to establish this as a viable long term alternative treatment for these patients.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Groote Schuur Ethics Committee, Cape-Town SA Erasmus Medical Center EC, Rotterdam Netherlands Melbourne Health EC, Melbourne Australia Sydney Adventist EC, Sydney Australia**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**