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VOIDING DYSFUNCTION SYMPTOMS RELIEF BY PELVIC FLOOR STIMULATION

Hypothesis / aims of study
Chronic urinary voiding dysfunction is a broad class of bladder conditions that covers a wide range of disorders, some of which cause pain, urinary frequency, urgency, urinary incontinence or other complications. We evaluated symptoms relief in two voiding dysfunction populations: (1) Interstitial Cystitis (IC), chronic symptom-complex of unknown aetiology, is characterized by irritating voiding symptoms and bladder pain and (2) Over Active Bladder (OAB) autonomous bladder contractions causing urgency, frequency with or without urge incontinence using intermittent pelvic floor stimulation.

Study design, materials and methods
Following the rules in the Declaration of Helsinki and after assigning free consent, 105 patients enrolled in two multi-national studies, determining the effect of a permanent implantable electrostimulator system on voiding dysfunction symptoms. The system consists of a pulse generator, implanted in the lower abdominal region, connected to a para-urethral stimulation lead. Evaluation was based on 3-day voiding diary, pain questionnaire and other relative quality of life questionnaires (QLQ) before and at 3 months post operation intervals. P less than 0.05 in a two-tails student's *t*-test was used to assess statistical significant at each evaluation point as compare to baseline.

Results
Eighty-four out of 105 enrolled female patients, age between 21 to 80 mean 57 years, had had system implanted. Of the 84, 61 were IC patients and the rest (23) OAB patients. For the IC study baseline urinary frequency was 24.1 times per day, pain level per Visual Analogue Scale (0-no pain 10-severe pain) was 5.9 and O'Leary-Sant (IC QLQ) score was 31.1. A significant reduction had been reported throughout investigation follow up, e.g. frequency, pain and O'Leary Sant were 17.9, 3.0 and 20.8 after 3 months of treatment 18.1, 2.8 and 19.8 post 6-months and 17.6, 2.8 and 17.4 at one year point (for all $p<0.05$), respectively. At the OAB study we evaluated the change in urinary frequency, degree of urgency, numbers of leakage episodes and quality of life. After an average of 20 months (range1-44) frequency decreased from 17.3 at baseline to 10.3 times at the last follow up visit ($p<0.01$), urgency on a scale from 0-none to 3 –severe urgency prior to voiding changed from 2.0 to 1.3 ($p<0.05$) and incontinence events decreased from 9.1 to 3.4 ($p<0.05$).

Interpretation of results
Though the significant improvement in subjective voiding dysfunction symptoms twenty-three out of the eighty-four implanted patients withdrew their consent and had their system removed. The main reasons were lack of efficacy and technical problems.

Concluding message
The promising results from those cohorts' studies demonstrate that pelvic floor stimulation is an effective treatment for the dysfunctional voiding and pelvic pain patients who are refractory to other conventional treatment.

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HUMAN SUBJECTS: This study was approved by the Groote-Schuur, Warsaw School of Medicine, Herlev Medical Center, San Crlo di Nancy, Erasmus Medical Center, UK -LREC and MREC, Souther health, Royal Melbourne Hospital and Sydney Adventist and followed the Declaration of Helsinki Informed consent was obtained from the patients.