A NOVEL DEVICE FOR THE TREATMENT OF THE OVERACTIVE BLADDER SYNDROME: MINIATURO-I

De Jong P R [1], Parsons M [2], Cardozo L[2], Nissenkorn I [3]
1. Department of Obstetrics and Gynecology, Groote Schuur Hospital, University of Cape Town, Cape To, 2. Department of Urogynaecology, Kings College Hospital, London England, 3. Department of Surgery/Urology, Sackler School of Medicine Tel-Aviv University, Tel-Aviv Israel

Hypothesis / aims of study

Overactive bladder syndrome (OAB) has been defined as urgency with or without incontinence, with frequency and nocturia in the absence of local pathological or hormonal factors (1). The purpose of the study was to assess the results of pelvic floor electrostimulation by a novel implantable electrostimulator, the miniaturo™-I system (BioControl Medical Ltd., Israel), in women with OAB.

Study design, materials and methods

Ten women (mean age 60 years, range: 50-75 years) with severe urgency-frequency symptoms gave written consent were enrolled into the study in two centres. All suffered frequency, nocturia, urgency and urge incontinence for at least one year, and failed conventional treatments, including behavioural and lifestyle modification, anti-cholinergic and anti-microbial therapy. During a simple surgical procedure (under epidural or local anesthesia), a pulse generator (size 53 x 47 x 11 mm) was implanted subcutaneously through a 4-5 cm suprapubic incision and secured to the rectus sheath. A bipolar stimulation lead was inserted paraurethrally and connected subcutaneously to the pulse generator. The system was activated via a telemetry device to deliver intermittent pulses through the lead to the pelvic floor with the intensity determined individually according to the patient's sensations. Urinary symptoms (frequency of micturition, urgency, incontinence episode frequency, pad use) quality of life of the patients (as measured using the Kings Health Questionnaire) were compared before and 1,3, 6 and 12 months after surgery. Urgency was measure with a Likert scale where 0=no urgency, 1=mild urgency, 2=moderate urgency, and 3=severe urgency. Possible complications were monitored. Ethics approval has been granted for this study.

Results

Ten patients completed an average of 10.5 months follow up (range: 3-18 months) post implantation. Four women were completely dry at the last visit and eight out of ten reported significant improvement in their quality of life. The following graph shows the improvement in patients' symptoms on an intention to treat analysis.

Two out of ten patients had their systems removed. One system was explanted 1 month after surgery, because the patient withdrew from the study, as she derived no subjective benefit. The other system was removed ten months post-surgery due to late infection. One lead replacement was performed due to lead displacement, and debridement and secondary closure of the para-urethral wound was performed due to slow wound healing in another. No other complications or adverse events have occurred.