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THREE-MONTHS RESULTS OF IMPLANT DRIVEN TIBIAL NERVE STIMULATION FOR THE TREATMENT OF OVERACTIVE BLADDER SYNDROME.

Hypothesis / aims of study

To investigate the safety and performance of an implantable system for tibial nerve stimulation as a treatment for overactive bladder (OAB) syndrome.

Study design, materials and methods

Included patients are part of a multicentre trial. This abstract will describe the 3 months results of the patients treated in our hospital.

In 15 OAB patients a battery free stimulation device for tibial nerve stimulation (BlueWind Medical,Herzliya, Israel) was implanted. The system composed of an implant, which is wirelessly powered by an external control unit (ECU) that controls the therapeutic parameters and is worn by the patient during treatment at home. A Physician Programmer is used to remotely set individual stimulation parameters for each patient to optimize therapeutic outcome. One month after implantation the system was activated using standard parameters, a pulse width of 200µsec and a frequency of 20Hz. The patient specific minimum amplitude was set at the amplitude of first sensation, and the maximum amplitude was set at the highest tolerable level. Patients were asked to stimulate 6 times a week for 30 minutes at a comfortable amplitude. Patients received an ECU in order to operate the implant and be able to adjust the amplitude between a patient specific set minimum and maximum. Follow up visits were planned 1 and 3 months after activation with a 3-day bladder diary and quality of life questionnaire. In addition to the multicentre protocol patients filled in a 3-day 24-hour pad test, ICIQ-FLUTS questionnaire and the patient perception of bladder condition (PPBC). The bladder diary contained frequency, micturition volume, fluid intake, and the number and severity of urinary urgency episodes (range 1-5, 5=high) as well as incontinence episodes (0= no leak, 1= drops, 2= small amount, 3=large amount). The ICIQ-FLUTS consists of 12 questions on bladder filling, voiding and incontinence. Each question allows five response options: '*never'* (0), '*occasionally*' (1), '*sometimes*' (2), '*most of the time*' (3), and '*always*' (4). The total sum score of the ICIQ-FLUTS ranges from 0-48 (asymptomatic to very symptomatic). Each question on symptoms is linked to a question on bother from 0-10 (no bother – maximum bother). The total sum score of the ICIQ-FLUTS on bother ranges from 0-120. The PPBC is a single-Item global measure for patients with OAB. Patients are asked to rate their perceived bladder condition on a 6-point scale. '*no problem at all'* (1), '*very minor problems'* (2), '*minor problems'* (3), '*moderate problems'* (4), '*severe problems'* (5), '*many severe problems'* (6). If necessary 1 month after activation the stimulation parameters were adjusted.

Results

Two males and 13 females were enrolled. Mean age was 54 years (range 19-72). Five/15 patients were previously treated with PTNS. Twelve/15 patients experienced urgency urinary incontinence (OAB-Wet). The median skin to skin operation time was 34 minutes (range 23-90). Although optional, all patients were operated under general anesthesia. In one patient no proper response was found after stimulation of the tibial nerve during the implantation procedure at patient's preferred side, therefore the device was implanted in the other leg. After implantation, 3 patients had a prolonged antibiotic treatment for 1 week and 3 patients used prolonged pain medication for 1 week. In one patient the implant was explanted due to pain and swelling suspicious of infection. The results of the other 14 patients were analyzed.

The **24 hours frequency decreased significant** (p=0.003) from 11.8 times/day (±3.5) at baseline to 9 times/day (±2.3) after 3 months. The mean micturition volume increased from 159ml (±58.7) to 177ml (±59.2). The amount of **heavy urinary urgency episodes (score>3)/day improved significant (**p=0.002) from 6.5 times/day (±5.1) at baseline to 2.0 (±2.1) at 3 months follow up. It improved with >50% in 13/14 patients.

In the OAB-wet patients two patient were completely dry at three months follow up. The number of urinary incontinence episodes/day decreased but not significantly from 7.24 (± 5.00) to 3.72 (± 3.65) (p=0.091). Four/11 had >50% improvement of urinary incontinence episodes/day. Nine/11 OAB-wet patients used pads. Mean **urine loss in grams/24 hours decreased significant** (P=0.038) from 243grams (± 388) to 39 grams (± 55). Five/9 had >50% improvement of their urinary loss in grams/24 hours. Seven/11 suffered from **severe incontinence episodes (score 3=large amount). This decreased significantly** (p=0.017) from 2.8 (±5.2) episodes/day to 0.3 (±0.4) episodes/day. Five/7 had >50% improvement of these severe incontinence episodes.

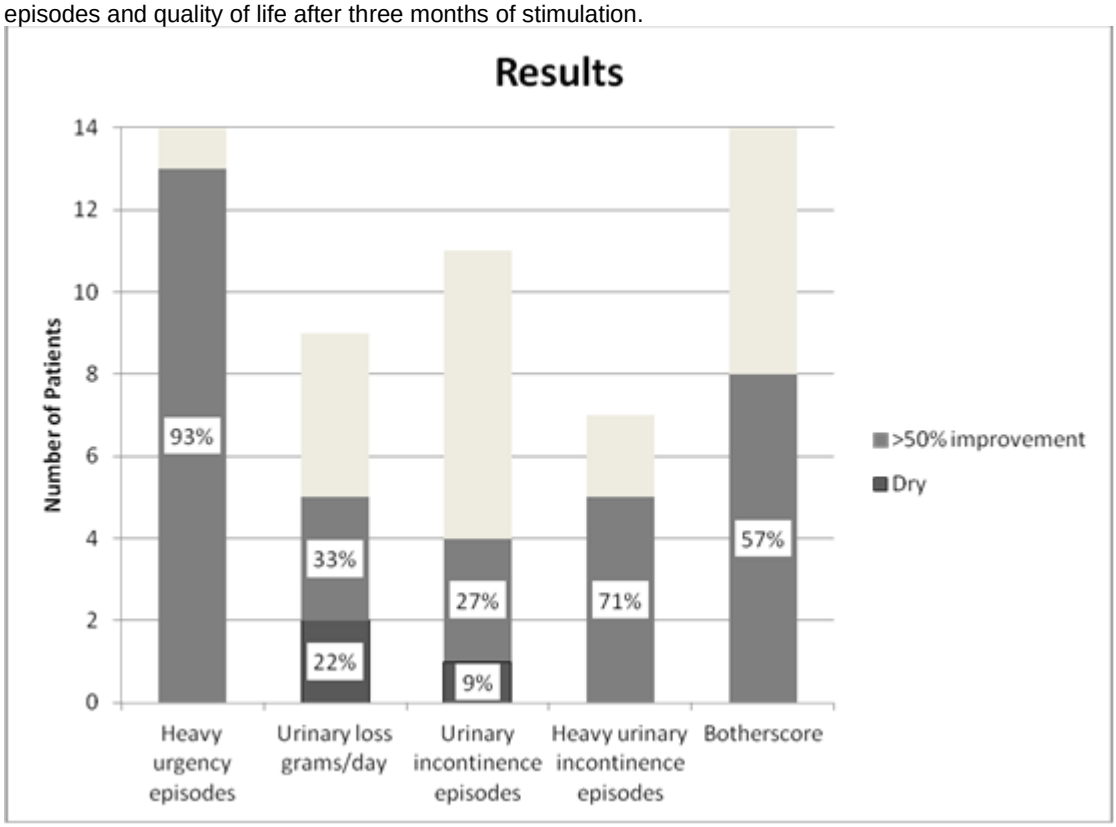
The quality of life questionnaire measured with the ICIQ-FLUTS improved significantly (p=0.002). In 13/14 the sum-score of the ICIQ-FLUTS improved, in one patient it remained unchanged. The bother-score improved in all patients. In 8/14 patients the bother-score improved with >50%. At baseline the FLUTS sum-score was 19 ±7 (range 10-32) with a bother-score of 58(±24). This decreased to a sum-score of 12 (±6)and a bother-score of 28 (±19) after 3 months. The PPBC improved in 12/14 patients, for the remaining 2 the PPBC remained unchanged. At baseline the PPBC was 5.0 (±1.1) after 3 months it was 3.7 (±1.3)

Interpretation of results

Clinically the BlueWind Medical tibial nerve stimulation system shows a decrease of the overall number of incontinence episodes/day and **a significant decrease of the amount of urinary loss/24 hour, 24-hour frequency, urinary urgency episodes/day, heavy urinary incontinence episodes/day and improvement of quality of life at three months follow up**. Only one patient (6%) experienced a serious adverse event in this easy to do procedure because the device was explanted, although tissue cultures did not show a bacterial infection.

Concluding message

The BlueWind Medical tibial nerve stimulation system is a safe and easy to implant stimulator. The clinical results show a significant improvement of 24-hour frequency, urinary urgency episodes, amount of urinary loss, heavy urinary incontinence episodes and quality of life after three months of stimulation.



Disclosures

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