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TIBIAL NERVE STIMULATION BY IMPLANT IN THE TREATMENT OF REFRACTORY OVERACTIVE BLADDER SYNDROME: 12-MONTH FOLLOW UP

Hypothesis / aims of study

Percutaneous Tibial Nerve Stimulation (PTNS) has been successfully introduced as a therapy for patients with refractory lower urinary tract dysfunction. Most patients that responded positively are in need of maintenance therapy. This is a big burden for both patients and caregivers at the outpatients' clinic. An implant, Urgent SQ™, has been designed for Subcutaneous Tibial Nerve Stimulation (STNS) that enables self-treatment at home. This study was designed to investigate feasibility, efficacy and safety of such an implant.

Study design, materials and methods

8 patients (6 women, 2 men, mean age 56 years) with refractory overactive bladder syndrome ($\geq$ 8 voids and/or $\geq$ 3 urge urinary incontinence episodes per 24 hours) were successfully treated with PTNS ($\geq$ 50% reduction of number of incontinence episodes and/or micturition frequency on bladder diary) and were deemed eligible for the study. Until implantation no maintenance therapy was performed (mean 3 months, range 8-12). The implant consists of an external stimulator (figure 1) and an internal body (figure 2) with two stimulation wires and unipolar electrodes. The stimulation parameters were 12 or 20 Hz, 200 microseconds and 0-19 mA. After spinal or general anaesthesia an incision of 5-7 cm was made approximately 5 cm above the medial ankle, parallel to the tibia. No muscle relaxants were used in order not to blur a motor response of the foot musculature. The internal body was placed in a subcutaneous pocket towards the tibia and after incising the fascia of the flexor tendons the electrodes were placed near the neurovascular bundle that contains the tibial nerve. During operation, activation of the implant confirmed correct placement by flexion of the big toe. Patients filled out bladder diaries and quality of life questionnaires (I-QoL) before implantation (T1) and at follow up of 6 (T2) and 12 months (T3) of STNS. At all visits physical examination and urinalysis were performed. The motor and sensory responses were evaluated at day 1 and 10 postoperative during follow up. Definition of successful treatment for STNS and PTNS were equal. Changes in voiding and quality of life parameters were tested on statistical significance using the Wilcoxon Signed Ranks Test.

Results

The procedure took an average of 25 minutes (range 20-30). The patients were discharged after 2 days of bed rest and leg elevation. STNS with the Urgent SQ™ device was started postoperative day 10, 30 minutes 3 times per week. At operation the motor response was present in all patients, postoperative day 1 in 2, day 10 in 0 and at T2 and T3 in 6 patients. The sensory response was present day 1 in 5 patients, day 10 in 6, at T2 in 8 and T3 in 7 patients. During follow up no adverse events like local infection, erosion or dislocation had occurred. At T2, 6 patients (75%) were successfully treated. Furthermore, 1 patient had a urinary tract infection and 1 patient had an unexplainable loss of efficacy and dropped out of the study. At T3, 4 patients (50%) were successfully treated. Of the 2 patients who lost the efficacy 1 patient was improved on bladder diary compared to T1, but did not meet the definition of success and 1 had an unexplainable loss of efficacy. The clinical results are presented in table 1.

Table 1.

Parameters per 24 hour	Mean (SD) T1* N=8	 T2** N=8	 T3*** N=7
Number of voids	14.4 (4.9)	10.9 (3.3)	11.6 (2.9)
Nocturia	2.9 (1.6)	1.6 (1.1)	2.1 (0.7)
Mean voided volume (cc)	123.8 (57.6)	119.4 (57.9)	154.1 (55.3)
Number of incontinence episodes	9.3 (13.5)	3.6 (7.3)•	1.9 (3.0)
Incontinence severity[1]	1.1 (1.0)	0.5 (0.8)	0.6 (0.8)
Number of used pads	2.9 (2.4)	1.6 (2.0)	2.1 (2.3)
I-Qol	64.1 (15.1)	86.5 (17.1)•	83.6 (17.2)

*baseline, ** 6 months of STNS, ***12 months of STNS, •p<0.05

[1]0= no urine loss, 1= loss of some drops, 2= loss of small amount, 3=change of clothes due to urine loss

Figure 1.

Figure 2.

Interpretation of results

This study shows that tibial nerve stimulation by implant is possible and fairly easy to do. In all patients a motor response could be obtained during surgery. In some patients, however, the motor response was no longer present after the operation. This was probably caused by thickness of the skin or edema or fibrosis around the electrodes. The latter could also have caused the loss of efficacy in 2 patients. 1 patient had a defective internal body and 1 patient never responded to STNS. STNS seems to be safe since no adverse events have occurred during the 12-month follow up.

Concluding message

Implant driven subcutaneous Tibial Nerve Stimulation with the Urgent-SQ™ is feasible and in this pilot study it seems to be safe in patients with refractory OAB. The efficacy seems to decline somewhat during follow up.

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