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WHAT TO DO IF PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS) WORKS? A PILOT STUDY ON HOME BASED TRANSCUTANEOUS TIBIAL NERVE STIMULATION

Hypothesis / aims of study

Percutaneous tibial nerve stimulation (PTNS) is a neuromodulation treatment of the lower urinary tract. Its efficacy on overactive bladder syndrome (OAB) has been recently confirmed by randomized controlled trials, producing a level 1 evidence of efficacy for this condition (1,2). Study on long term results of PTNS have been performed as well, demonstrating that, with periodic stimulation sessions, its efficacy is maintained at a follow up of 12 months and longer (3). Unfortunately, for economic and organizational reasons, it is difficult to perform the stimulation sessions for a long period of time in an office setting. Aim of this pilot study was to assess the feasibility of a home based transcutaneous tibial nerve stimulation protocol.

Study design, materials and methods

Sixteen patients (13 F; 3 M, mean age 49,5±11,9 years) with OAB (6/16 with urgency incontinence), considered responders to PTNS, were included in this pilot study. These responders patients had showed a ≥ 50% reduction of urgency or (if incontinent) urgency incontinence episodes/day after PTNS (30 minute stimulation, performed twice a week) and were willing to continue the treatment. After signing an informed consent, patients were asked to perform, at home, a flexible protocol of transcutaneous tibial nerve stimulation (TTNS): number and timing of the stimulation sessions was left to patients' decision, whilst the technique of stimulation was established (30 minute sessions, performed with preset electric parameters (frequency 20 Hz; width 200 μs) and using a patch electrode located approximately 5 cm cephalad to the medial malleolus. Patients were instructed and performed the first transcutaneous stimulation session at the hospital offices. Data coming from bladder diaries and a questionnaire on quality of life (I-QoL) were recorded every 3 months and compared with data obtained before and after PTNS. Number of stimulation performed per week was also recorded. Patients satisfied of the home based treatment were considered "subjective responders"; patients not showing a ≥10% increase of urgency/urgency incontinence episodes/day in comparison to post PTNS results were considered "objective responders". Number of drop-out was recorded as well.

Results

Two patients (1 M and 1 F) stopped the home treatment for personal reasons. For the remaining 14 patients, mean follow-up was 19,7 (6-30) months. For 10/14 patients 12 month follow up was available. All patients were considered subjective responders; all but one incontinent patient were considered objective responders. Mean number of stimulations performed per week was 1, 6 (1-3). Results are reported in table 1.

Tab. 1

	A Baseline	B After PTNS	C After TTNS	p B vs. A	p C vs. B
Number of urgency episodes/day (5 patients) (mean)	7,4	2,7	2,6	0.08	Ns
Number of urgency incont. episodes/day (7 patients) (mean)	4,1	1,0	1,0	0.02	Ns
Nocturia episodes (mean)	2,8	1,8	1,5	0,01	Ns
I-QoL (mean)	51	76	82	0,03	Ns

Interpretation of results

After this pilot study, it is possible to conclude that home based TTNS is feasible. Only 2/16 (12,5%) decided to stop the protocol; all the remaining were satisfied at a mean follow of 19 months. 10/14 patients were followed up for a period of time ≥ 12 months. Results obtained are encouraging, with 13/14 patients considered objective responders, and with a substantial stability of bladder diaries parameters and I-QoL score.

Concluding message

Home based TTNS is feasible and preliminary results seem promising. A randomized controlled trial comparing results of a PTNS office based protocol of stimulation with results of home based TTNS is needed, to assess if this last treatment could be the ideal solution for the long term treatment of patients responding to PTNS.

References

1. J Urol. 2010 Apr;183(4):1438-43.
2. J Urol. 2010 Nov;184(5):2001-6.
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Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**