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HOME BASED THERAPEUTIC APPLICATION OF NON-INVASIVE POSTERIOR TIBIAL NERVE STIMULATION IN THE TREATMENT OF OVERACTIVE BLADDER SYMPTOMS: A PILOT CLINICAL TRIAL

Hypothesis / aims of study
To determine whether self-administered, non-invasive posterior tibial nerve stimulation (PTNS) using a conventional TENS machine may be effective in patients with idiopathic overactive bladder symptoms, and thus should be considered for larger clinical evaluation.

Study design, materials and methods
This parallel, randomized and home based pilot clinical trial was conducted between June 2013 and December 2014. Patients with idiopathic overactive bladder symptoms who had not responded or could not tolerate (due to side effects) conventional drug therapy, were randomized into one of three stimulation groups (unilateral PTNS, bilateral PTNS and sham stimulation). Participants were able to remain on stable medication throughout the trial and those with urinary retention, clinically significant voiding lower urinary tract symptoms or stress predominant mixed urinary incontinence were excluded. The participants had to present with at least 8 micturitions in the baseline in order to be randomized. The full list of inclusion and exclusion criteria and details of the trial is at trial registry.

All groups self-administered 40 minutes of electrical stimulation every day over a 4 week period, using a conventional TENS machine and a pair of adhesive surface electrodes and a stimulus intensity just below that which would cause a motor contraction of toes/shoulder muscles. The unilateral stimulation group placed the electrodes above and below the medial malleous on the right ankle, the bilateral stimulation group placed the electrodes on the same position as unilateral stimulation group but on the both ankles. The sham stimulation group placed the electrodes on the anterior aspect of the left shoulder.

The study was presented to the participants as a comparison of three different site of stimulation (right ankle, both ankles and left shoulder) in order to blind participants to the fact that transcutaneous PTNS was being investigated. The participants were unaware that one of the stimulation groups was considered as a placebo group. The researcher who provided the training to participants was not blinded as to the intervention to which the participants were allocated. The research team did not interact with participant's outcome questionnaires and bladder diary, and the data were recorded only by the participants. Randomization was computer-generated, with allocation concealment by opaque sequentially number sealed envelopes stratified by the number of micturitions per 24h at baseline into two groups (< 15 and ≥ 15).

Participants were assessed using standardised OAB questionnaires and a 3-day bladder diary: at baseline; after the first week; after four weeks of stimulation; and four weeks after stimulation ended. Primary outcome measurements of the study were the mean change in the number of micturations and urgency episodes per 24h. Responders were defined as those who showed a combination of a >30% reduction in total daily micturitions and/or urgency episodes as compared to baseline and a self-reported subjective improvement of their condition.

Results
Altogether 22 participants commenced the study protocol. However one participant decide to discontinue the treatment period and two participants were excluded from analyses, because they did not follow the study protocol also significantly affected that fluid intake during the study. Therefore 19 patients (9 men and 10 women) with a mean age of 59±7.9 (mean ± SD) who finished the full study protocol were randomized into bilateral transcutaneous posterior tibial nerve stimulation ((TPTNS) n=6), unilateral TPTNS (n=7), or sham stimulation (applied to shoulder, n=6).

Mean number of micturitions per 24h decreased by 2.8 (95% CI, -6.7 to 1.1) in the bilateral treatment group; 1.7 (-9 to 3.7) episodes in the unilateral treatment group and 0.7 (-2.1 to 6.3) in the sham stimulation group. Similarly mean number of urgency episodes decreased by -3.2 (-8.5 to 2.1) in the bilateral stimulation group, by -1.3 (-5.0 to 2.2) in the unilateral stimulation group and by -0.7 (-5.0 to 3.7) in the sham stimulation group.

3/7 participants in the unilateral stimulation group, 2/6 in the bilateral stimulation group and 1/6 patients in the sham group met the criteria to be identified as responders to treatment. Initial effects were reported after the first week of the therapy in all responders. In the majority of responders the effects ceased at the follow-up visit, four weeks after therapy had finished.

Interpretation of results
This pilot trial demonstrates that there are patients who may benefit from this non-invasive type of therapy, which shows similar results to those obtained in percutaneous PTNS using a needle electrode [1]. However, the technique presented here is completely non-invasive, can be self-administered by the patient at home and is thus low cost. Although the effects do not seem to be large they, if confirmed by a larger study, are comparable to the success rates observed in the latest OAB drug trials [2].

Furthermore, this non-invasive stimulation has no significant side effects and hence may potentially offer a useful additional treatment option for these patients. Participants in this trial had severe OAB symtpoms despite numerous drug therapies and

would usually be offered more invasive treatments such as Botolinium Toxin injections or sacral neuromodulation in order to manage their symptoms. Therefore TPNTS may be seen as an attractive alternative, particularly for those who are either unwilling to perform intermittent self catheterisation or unfit to undergo operative management.

Concluding message

Transcutaneous PTNS might be an effective option for patients with overactive bladder symptoms. A fully-powered randomized and multi-centre clinical trial investigating effects of this form of stimulation in various patient populations is now needed to determine if this treatment options should be considered for routine clinical use.

References

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Disclosures

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