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SINGLE CENTRE RANDOMISED PILOT STUDY OF TWO REGIMENS (30MINS DAILY OR 30MINS WEEKLY FOR 12 WEEKS) OF TRANSCUTANEOUS TIBIAL NERVE STIMULATION FOR THE TREATMENT OF PATIENTS WITH OVERACTIVE BLADDER (OAB) SYNDROME

Hypothesis / aims of study
The aim of this study was to evaluate the clinical efficacy of a novel transcutaneous device for the treatment of patients with either multiple sclerosis or idiopathic OAB. A transcutaneous device, effective at treating OAB, with minimal side effects and simple enough for patients to self treat at home, would be very a convenient addition to the armentary of therapy available. The geko™ is a discrete, self-contained and portable, CE marked device that sticks to the skin.

Study design, materials and methods
A randomized, single centre, phase II pilot study, which enrolled 48 patients (24 with MS and 24 with idiopathic OAB), suffering from OAB. Patients were randomized into either daily or weekly treatment arms. Both arms involved 30 minutes of stimulation for 12 weeks. Objective outcome measures were used to evaluate symptoms at baseline, week 4, 8, and 12. This included the ICIQ-OAB, ICIQLUTS-QoL, bladder diary scores and urinary neurotrophin levels (Nerve growth factor (NGF) and Brain derived neurotrophic factor (BDNF)) were also measured at baseline, week 4 and 12.
Ethics committee approval was obtained prior for the study.

Results
Forty eight patients were recruited into the study, with 35 five patients completing (20 with MS and 15 idiopathic OAB). Multilevel regression analysis shows significant improvements in the ICIQOAB by -10.2 (-13.5 to -6.9) (p=0.001) and ICIQLUTS-QOL by -40.8 (-57.4 to -24.3) (p=0.000) scores for both patient groups by week 12. Weekly treatment seemed equivalent to daily, There were no significant adverse effects. Likert scales showed that patients rated the treatment as easy to use, comfortable, and were very satisfied wth this as a treatment modality.
Neurotrophins
In patients with Idiopathic OAB who responded to therapy, mean NGF/Creat levels were 11.3 (2.7-18.9) and 13.6 (1.8-22.4) pg/mg at baseline and week 12 respectively (p=0.99). Non-responders had mean levels of 96.6 (40.6-97.8) to 48.4 (4.5-133.6) pg/mg at baseline and week 12 respectively (p=0.23). The NGF/Creat levels at baseline were significantly different between the responders and non-responders (p=0.05).
In patients with Idiopathic OAB who responded to therapy, mean BDNF/Creat levels changed from 66.6 to 19.1pg/mg (p=0.03). Non responders had a change of mean levels from 117.7 (6.7-337.8) to 76.8 (0-182.5) pg/mg at week 12 (p=0.89).
There was no significant changes in the urinary NGF/Creat or BDNF/Creat scores from baseline to week 12 for the patients with MS and OAB.

Interpretation of results
Significant improvements were seen in subjective and objective symptom assessment parameters for patients using this novel form of tibial nerve stimulation. Adverse effects were minimal. Weekly treatments were equivalnt to daily. Urinary neurotrophin assessment in the idiopathic OAB group shows that perhaps higher levels of NGF/Creat at baseline may be a predictor of poor response, whilst urinary BDNF/Creat levels could be investigated further to monitor response to treatment as they significantly reduce in the patients who respond to therapy. Urinary Neurotrophin levels did not change significantly in the patients with MS during treatment.

Concluding message
This randomised pilot study shows that transcutaneous tibial nerve stimulation, using the geko™ device, appears to be an effective, safe and convenient method of management for patients with severe OAB symptoms. Additional work is required to demonstrate the long-term efficacy of this treatment.

References
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Disclosures
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