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O'Reilly B[1], Achtari C[2], Hiscock R[2], Murray C[2], Thomas E[2], Fynes M[2], Dwyer P[2]
1. Cork Univerity Hospital, 2. Mercy Hospital for Women, Melbourne, Australia

A PROSPECTIVE RANDOMISED DOUBLE-BLIND CONTROLLED TRIAL EVALUATING THE EFFECT OF TRANS-SACRAL MAGNETIC STIMULATION IN WOMEN WITH OVERACTIVE BLADDER

Hypothesis / aims of study

Overactive bladder (OAB) is a prevalent condition with 16% of adults having one or more symptoms that significantly affect quality of life. Standard drug treatments for the OAB have been shown to be of limited efficacy, which has led to research into other forms of therapy, especially in the treatment of patients with intractable symptoms that have not responded to pharmacotherapy, including transcutaneous electrical nerve stimulation and implantable sacral neuromodulators. Both of these treatment modalities have had success but are expensive and invasive. An alternative neuromodulatory technique involves the use of electromagnetic stimulation of the sacral nerve roots. These studies have involved the use of cumbersome, hospital-based devices and have acknowledged the influence of placebo effects. We have developed a portable electromagnetic device (with a corresponding sham unit) to overcome these problems. Trans-sacral stimulation of the S3 and S4 sacral nerve roots is achieved using a small device incorporated into a belt. The device operates at a pulse rate of between 5 and 20Hz with a pulse width of 1ms producing a magnetic field of 200 Gauss. This is produced by twin coils of 50 mm diameter with a timer set at 20 mins. The device is powered by two 12-volt rechargeable batteries. Activation of the device will induce specifically pulsed magnetic energy. The general principle is that a very low frequency - low power complex, forming pulses of electromagnetic energy forces, are introduced into the S3 and S4 sacral nerve roots which modulate bladder activity, subjecting these nerves and surrounding cell tissues to changing electric potentials with a speculated increase in inhibitory neuronal impulses to the bladder (detrusor) muscle.

The aim of this study was to evaluate the impact of trans-sacral electromagnetic stimulation on OAB symptoms in women.

Study design, materials and methods

The study was a prospective double-blind randomised controlled study. Following a power analysis, women with symptoms of OAB were prospectively recruited with ethical approval for randomization to an active treatment (n=33) or placebo group (n=30) in a double-blind trial. The patient, at home, used the belt device daily for 20 minutes over 12 weeks. Outcome measures included a three day voiding diary, 1 hour pad test, visual analogue score (VAS) for symptom impact (0-100%), Kings Health Questionnaire (KHQ) and Australian Quality of Life questionnaire (AQOL) at baseline, 6 weeks and 12 weeks.

Results

Overall no difference was found between groups for any of the research questions. Specifically, we were unable to demonstrate any difference between the active and sham device groups in frequency, nocturia, urinary leakage, or quality of life, nor was there any evidence of a placebo effect. The quality of the data was high with the number of missing observations (especially for disease specific KHQ and general AQOL) being low.

Interpretation of results and concluding message

Trans-sacral electromagnetic neuromodulation when used in a double blind randomised controlled trial has no effect on the symptoms of OAB.