EXTRACORPOREAL MAGNETIC INNERVATION (EXMI™) FOR TREATMENT OF URINARY INCONTINENCE IN A POPULATION OF EUROPEAN PATIENTS

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Background. Extracorporeal Magnetic Innervation therapy (ExMI) is a non-invasive method of provoking depolarization of nerves and muscles in the pelvic floor, resulting in muscle contraction. It is hypothesized that ExMI helps to build muscle mass and strengthen the pelvic floor muscles and sphincters.

Objective. This multi-centre study reports the effects of ExMI on the pelvic floor and urinary sphincter for patients with pelvic floor dysfunction, including urinary incontinence. The study was double-blinded, randomized and placebo-controlled.

Subjects. Eligible patients were males and females over age 20 with demonstrable stress urinary incontinence, urge incontinence (including urethral instability) or mixed incontinence. All patients wore pads for protection. Randomization was conducted by phone through an independent body.

Methods. Patients sat fully clothed in the NeoControl chair over a pulsed magnetic field that stimulated muscle contractions in the pelvic floor region. Patients were treated 3 times a week for 6 weeks. Each session lasted 23 minutes, which included 10 minutes of intermittent low frequency stimulation (5 Hz), a 3-minute rest period and 10 minutes of intermittent high frequency stimulation (50 Hz). No power was applied during placebo treatment and, therefore, no magnetic field was created. Patients were told that the magnetic field operates silently, similar to a CAT scanner.

The outcome measures, which included ICS pad-weight tests and pad use, were collected at baseline and at 8 weeks.

Results. Of the 49 patients enrolled, 24 were randomized to active treatment and 25 to placebo. 14 (58%) patients from the active treatment group and 19 (76%) patients from the placebo group completed 8 weeks. Dropouts were due to patients who missed treatments and were excluded. No related adverse events were reported (one patient complained of back pain during treatment).

There was a reduction in leaks after running in place for 1 minute (p=0.002). At 8 weeks, 86% of active patients did not leak (up 15% from baseline). The placebo group had more leaks at 8 weeks (from 47% leaking at baseline to 68% at 8 weeks).

Patients' ability to sit and rest for 30 minutes after drinking 500ml of liquid improved (p=0.09). At 8 weeks, no active treatment patients leaked (up 21% from baseline); there was no change in the placebo group, with 21% leaking.
There was a difference in pad weight between the two groups at 8 weeks (p=0.079). Patients receiving active treatment had a mean pad weight of 2.59g, whereas patients receiving placebo had a mean pad weight of 14.67g.

Quality of life (QOL) scores for patients receiving active treatment improved significantly from a mean of 72.86 at baseline to 84.69 at 8 weeks (p=0.04). No difference was shown in the placebo group (p=0.56).

Mean pad use for patients receiving active treatment changed significantly from 3.33 at baseline to 2.0 at 8 weeks (p=0.02).

Conclusions. Patients receiving active treatment showed improvement on several outcome measures. No improvement was demonstrated in the placebo group. Few conservative, non-invasive options for treating urinary incontinence exist. ExMI therapy is effective in improving urinary incontinence symptoms, making it a viable treatment option.