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Title: A DOUBLE BLIND RANDOMISED TRIAL COMPARING MAGNETIC STIMULATION OF THE PELVIC FLOOR TO SHAM TREATMENT FOR WOMEN WITH STRESS URINARY INCONTINENCE.

Aims of Study:

Magnetic stimulation is a non-invasive method of provoking depolarisation of nerve and muscle, thereby conserving muscle mass following nerve injury and potentially building muscle strength. One application of this is in the treatment of pelvic floor and urethral sphincter weakness in Genuine Stress Urinary incontinence. The use of an extracorporeal magnetic stimulation (ExMI) chair has been previously demonstrated for this indication with patients with Genuine Stress Urinary incontinence. The purpose of this randomized double blind trial was to compare the effects of ExMI of the pelvic floor utilising a sham treatment for women with genuine stress urinary incontinence to ascertain its usefulness in this condition.

Methods:

70 female patients were enrolled and underwent baseline evaluations including IQOL and Kings Health questionnaires; 3 day voiding diary;20 minute stress and 24 hour pad tests; video urodynamics and pelvic floor assessment prior to being randomised to either sham (n=35) or treatment (n=35). Patients were well matched in both groups at baseline. All patients undertook low intensity home based pelvic floor muscle exercises supervised by a urotherapist. Both the investigator and the urotherapist were blinded to patient grouping. No patients had previously undergone incontinence or pelvic floor surgery, and patients with significant pelvic floor prolapse were excluded. The treatment consisted of 16 treatments over 6 weeks (3 per week) for 20 minutes. The active arm received 10 mins at 10Hz (5 seconds on, 5 seconds off) and 10 minutes at 50Hz (5 seconds on, 5 seconds off). The sham arm received 16 “treatments” with a thin aluminium deflective plate inserted in the modified chair. Baseline evaluations were repeated at 8 weeks with any adverse events recorded.

Results:

	Baseline	8 Weeks
Active (n = 35)		
20 min pad test (ml)	39.5 $\pm$ 5.1	19.4 $\pm$ 4.6**
24 hr pad test (ml)	24.0 $\pm$ 4.7	10.1 $\pm$ 3.1*
QOL (I-QOL)	63.7 $\pm$ 2.8	71.2 $\pm$ 3.3**
QOL (Kings)	9.6 $\pm$ 0.8	6.9 $\pm$ 0.7***
Peritron	17.3 $\pm$ 1.8	19.2 $\pm$ 2.0
PFX	1.6 $\pm$ 0.3	2.7 $\pm$ 0.4*
Pelvic Floor assessment	5.0 $\pm$ 0.4	5.3 $\pm$ 0.4
Pads/day	0.9 $\pm$ 0.1	0.6 $\pm$ 0.1*
Sham (n=35)		
20 min pad test (ml)	39.9 $\pm$ 7.4	32.4 $\pm$ 6.7
24 hr pad test (ml)	37.2 $\pm$ 7.2	22.0 $\pm$ 5.2**
QOL (I-QOL)	62.6 $\pm$ 4.0	67.3 $\pm$ 4.4*
QOL (Kings)	9.7 $\pm$ 0.9	8.6 $\pm$ 1.0
Peritron	15.5 $\pm$ 1.9	15.1 $\pm$ 1.9
PFX	1.7 $\pm$ 0.3	1.9 $\pm$ 0.4
Pelvic Floor assessment	4.4 $\pm$ 0.4	4.6 $\pm$ 0.4
Pads/day	1.2 $\pm$ 0.2	1.0 $\pm$ 0.1

* $p < 0.05$ ** $p < 0.01$ *** $p < 0.001$

Whilst both groups improved significantly from baseline, there was no significant difference between the active and sham groups at 8 weeks compared to baseline for any parameter.

The mean baseline abdominal leakpoint pressure was 83.4 (50-140) cmH_2O in the active group and 76.3 (30-120) cmH_2O in the sham group. This value was the lower of the valsalva leak point pressure and the cough leak point pressure. At 8 week assessment 6 patients (17%) of the active patients did not leak at urodynamics compared to 3 patients (9%) in the sham arm. The mean values at 8 weeks for the remaining patients were similar to baseline values. The change was not significantly different between the two groups.

Patients who were unable to generate an adequate pelvic floor contraction at baseline were compared. They were defined as: A CVM rating of 3 or less; Perineometry $\leq$ 10 $cmsH_2O$ (Peritron); Perineometry $\leq$ 0.5 $cmsH_2O$ (PFX). There was significant difference demonstrated in the 20 minute pad test results in the poor performance patients for each of the above three variables in favour of the active group.

Associations between outcome variables were also examined using the baseline data. Neither QOL questionnaire correlated with either the 20 min or 24 hr pad test through the two questionnaires themselves were significantly correlated $r = -0.632$ ($p < 0.001$). The total CVM score was significantly correlated with both the Peritron and the PFX recordings and the two perineometers were closely correlated ($p < 0.001$).

The results of the two pad tests were not correlated ($r = 0.198$) and neither the pelvic floor muscle assessment nor the perineometry pressures correlated with either pad test result.

Conclusions:

Magnetic stimulation of the pelvic floor (ExMI) is an effective treatment for stress urinary incontinence in women unable to generate an adequate pelvic floor contraction. PFMT as we employed it is not beneficial in this group of patients. Follow up of both groups of patients is continuing to establish treatment durability.

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