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CLINICAL EFFICACY OF EXTRACORPOREAL MAGNETIC INNERVATION VERSUS PELVIC FLOOR MUSCLE TRAINING WITH BIOFEEDBACK FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN.

Hypothesis / aims of study

The treatment of urinary incontinence (urge, stress and mixed) consists of conservative and operative techniques. Besides Kegel exercises, biofeedback, vaginal cones and drug therapy conservative treatment also includes a variety of neurostimulation methods, such as electro- and magnetic stimulation. Electrical stimulation has been employed to treat stress and urge incontinence since the 1960s, with variable success rates. The negative aspect of electrostimulation is using a probe in the vagina or anus. In addition, vaginal bleeding, discomfort, local pain or irritation of surface patch electrodes has been reported to occur. Therefore, these factors make the treatment unattractive for women with urinary incontinence. Extracorporeal magnetic innervation (ExMI) is a new technology used for pelvic muscle strengthening for the treatment of urinary incontinence. ExMI has a physiological mode of action similar to that of electrical stimulation, but is non-invasive and painless and patients do not need to undress for the treatment. This makes the treatment more attractive than electrical stimulation. The aim of this study was to evaluate the clinical efficacy of extracorporeal magnetic innervation and compare the effect of ExMI and pelvic floor muscle training (PFMT) with biofeedback for the treatment of stress urinary incontinence in women (SUI).

Study design, materials and methods

80 women with mild and moderate SUI were included in a prospective study. All patients were evaluated by means of a detailed history of incontinence, a gynecologic examination and urine culture. Women with a history of neurological diseases, pacemaker or metal implants, arrhythmia, or pregnant, were excluded. The medical history and any previous treatment were noted. A voiding diary, a pad test, a perineometry were completed at baseline and at the end of the study to evaluate severity of incontinence and effect of the treatment.

Pelvic floor muscle strength was assessed by perineometry, using a PFX_2™ unit. Perineometry measures were recorded over a 3 second maximum voluntary contraction. After initial assessment participants were assigned to either an ExMI or PFMT with biofeedback group. Patients with rate of perineometry 2 conventional units or lower were put to an ExMI group. Patients with rate of perineometry 3 conventional units or higher get treatment by PFMT with biofeedback. ExMI therapy was performed for 20 min at 50 Hz twice a week for a total of 8 weeks. For treatment the patients were seated on a special chair containing a magnetic field generator (Neocontrol®, Neotonus, USA). PFMT with biofeedback was realized, using Uroproctocor™ (Invitro®, Russia). Patients were treated with 20 min twice weekly for 8 weeks.

Results

The mean age of women enrolled in the study was 44±10 (28–65) years. The cumulative success rate (cure + improvement) for ExMI and PFMT groups was 70% and 77.5%, respectively. The pad test after therapy for all patients showed an improvement in the loss of urine. In 14 (35%) of the 40 patients in ExMI group incontinence improved; 14 (35%) were completely dry. In PFMT with biofeedback group 4 (10%) patients were cured and 27 (67.5%) were improved. The pelvic floor muscle strength score was significant higher and pad weight was significant lower in both groups before and after treatment (Table 1).

Table 1. Results of perineometry and pad test for the ExMI group and PFMT with biofeedback group.

	Before treatment	After treatment	p value*
Perineometry (mean+SD)			
ExMI (40)	1.53±0.51	5.98±2.33	0.0001
PFMT with biofeedback (40)	4.1±0.81	6.7±1.51	0.0001
Pad test (mean+SD)			
ExMI (40)	7.83±3.31	2.88±1.2	0.0001
PFMT with biofeedback (40)	7.75±1.92	2.98±1.31	0.0001

*t-test

A voiding diary reported a significant reduced in number of incontinence episodes from 1.38±0.55 to 0.45±0.02 in ExMI group (p=0.0001) and from 1.43±0.78 to 0.6±0.05 in PFMT with biofeedback group (p=0.0001).

Interpretations of results

This study showed that women who undertook 8 week intensive ExMI and PFMT program demonstrate a similar improvement in incontinence symptoms. Both ExMI and PFMT with biofeedback are effective treatments for women with mild and moderate SUI. However, ExMI treatment especially effective in female patients with SUI who could not actively flex their pelvic floor musculature during PFMT and whose rate of perineometry were low.

Concluding message

Results of the survey have demonstrated that in order to reach the maximum effect from the healing it is required the differential approach of the healing depending on pelvic floor muscle strength.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This study was approved by the Moscow Medical Academy named by I.M. Sechenov Local Ethics Committee and followed the Declaration of Helsinki informed concent was obtained from the patients**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**