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Original Research

Impact of pulsed electromagnetic field on mixed incontinence in parous women a prospective randomized study

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Abstract

Background: This study was conducted to determine the impact of a pulsed electromagnetic field (PEMF) on mixed incontinence. This condition can have a significant impact on women's quality of life and social relationships. **Methods**: Parous females (n = 40) with mixed incontinence were randomly assigned to one of two groups. Group A received PEMF and pelvic floor muscle training in addition to general advice for 12 sessions. Group B received the same program but without PEMF. Pelvic floor muscle strength and the severity of urinary incontinence were assessed using a perineometer and the incontinence symptom severity index (ISSI), respectively. **Results**: Within groups comparison show statistically significant improvement in priniomter and severity index after treatment in comparison to pre treatment values. Between groups comparison after treatment showed better improvement in group A ($p < 0.05$) in pelvic floor muscle strength and a significant decrease ($p < 0.05$) in the severity of urinary incontinence compared to group B. **Conclusions**: PEMF combined with pelvic floor muscle training is an effective, convenient, and acceptable way to manage mixed incontinence.

Keywords: PEMF; mixed incontinence; perineometer

1. Introduction

Urinary incontinence is the involuntary leakage of urine that negatively impacts one's quality of life and occurs in a variety of forms. The involuntary flow of urine caused by effort such as coughing or sneezing is known as stress urinary incontinence (SUI). Urge urinary incontinence (UUI) on the other hand is the uncontrolled loss of urine that occurs simultaneous with or immediately after urgency. Mixed urine incontinence (MUI) affects women when they experience both stress and urge sensations [1].

MUI affects one out of every three women and involves both physical effort, which raises the intra-abdominal pressure, and urinary urgency [2]. Compared to pure UUI or SUI, MUI is more common in older females and has a bigger impact on a woman's quality of life [3].

Damage to the muscles, nerves and connective tissue of the pelvic floor causes the symptoms of SUI. Important factors for continence include urethral support, vesical neck function, and urethral muscle function [4].

A woman's level of SUI is very subjective and unique to each individual. Women who experience only light urine leakage during vigorous activity such as sport or after sneezing, laughing, coughing, or lifting are deemed to have moderate incontinence. Larger amounts of urine loss associated with low-impact activities such as standing, walking or leaning down are classified as moderate to severe SUI [5].

UUI is the uncontrolled loss of urine that occurs when there is a sense of urgency. If there is no underlying urinary tract infection or other evident pathology, UUI is considered to be part of a larger symptom complex known as overactive bladder syndrome. This is characterized by urine leakage and is frequently accompanied by nocturia, with or without UUI [6].

Urinary incontinence is sometimes linked to recurrent urinary tract infection, which is a curable cause of the condition. SUI and UUI are both associated with a higher body mass index and older age. Women with incontinent mothers or sisters are also more likely to experience SUI and MUI [7].

Supportive structures for the bladder neck and urethra are required to maintain urethral closure pressure. The levator ani (LA) muscle creates a powerful shelf that remains stable during the high forces generated by coughing or sneezing. SUI can be triggered by disruption of this shelf through weakening of the LA. The main etiological causes for LA muscle weakening are ageing and childbirth damage [8].

The first line of conservative care for women with MUI includes weight-reduction, behavior modification, pelvic floor muscle training, reduction of fluid intake, and caffeine restriction [9].

Pulsed electromagnetic field therapy (PEMF) conveys pulsed electromagnetic energy through two steel surgical probes applied to the skin. It is used to treat many musculoskeletal abnormalities [10].

PEMF affects numerous physiological mechanisms, improves circulation and increases the permeability of cell membranes. It shows good results for wound healing, the alleviation of muscle soreness, and in reducing the loss in range of motion after exercise. PEMF also has positive effects on muscle strength, muscle temperature, blood flow and oxygenation [11].

Urinary incontinence adversely affects the psychological and social wellbeing of females. Whereas surgical intervention for incontinence can lead to numerous complications, magnetic field therapy is considered to be a non-invasive technique for stimulating the nervous system [12]. So far, however, there are no published reports on the impact of PEMF treatment for MUI. The aim of the present study was therefore to assess the effectiveness and safety of PEMF for the treatment of such cases.

2. Subjects

This study was carried out on 40 parous women aged between 40 to 55 years and with a BMI ranging from 24 to 32 Kg/m^2. They were referred with either mild or moderate SUI symptoms associated with urgency. The women were diagnosed by a physician as having MUI, the current International Continence Society guidelines define MUI as a complaint of the involuntary loss of urine during exertion, sneezing, or coughing, as well as leakage associated with urgency,the diagnosis of MUI by a physician based on clinical history, this includes onset and timing of stress and urge symptoms, history of any urinary tract infections or sexually transmitted diseases, an obstetric history, bowel function, a frequency-volume diary, physical examination findings, pelvic examination should include evaluation of urethral mobility, pelvic organ prolapse, and urogenital atrophy, patients were selected from the outpatient clinic of the gynecological department of kafr elshiekh hospital, Egypt. This study was approved by the ethics committee of the Faculty of Physical Therapy, KFS El Sheikh University (No.: P.T./WH/7/2021/11).

Women with any dysfunction or associated injuries, or with any pathological conditions such as cardiac abnormalities, recurrent urinary tract infections, hypertension or diabetes mellitus, malignancy, cardiac pacemakers, TB, epileptics or hysterectomy were excluded from the study.

Following an orientation session describing the aim of the study and explanation of the treatment protocol, randomization was performed using a computer program (Microsoft Excel 2010). None of the participants withdrew from the study after randomization and each female gave written consent before treatment. The randomization procedure was performed through a computer program (Microsoft Excel 2010) that created a random table of numbers in which each number corresponded to the group A or B. After that, participants were allocated according to the corresponding number of their allocation code. A researcher was conducted the drawing procedures without informing participants and evaluators, to determine which was in group A or group B.

Women were randomized into two groups of equal size (n = 20). Group A received PEMF in addition to 12 sessions of pelvic floor muscle training and general advice conducted every other day, while group B received the same program but without PEMF.

2.1 Evaluation procedures

After taking a detailed history from each patient, pelvic floor muscle strength was assessed by a perineometer and the severity of urinary symptoms was assessed using the incontinence symptom severity index (ISSI). This evaluation was repeated at the end of the treatment program.

A perineometer (Peritron 9300, Cardio Design Pty Ltd, Australia) was used to assess pelvic floor strength before and after treatment for four weeks. This instrument comes with a vaginal sensor (28 mm diameter) and has a 0–300 cm H2O numerical readout. It was used to objectively measure the strength of pelvic floor muscle contractions before treatment and after 12 sessions of treatment, as well as for muscle re-education and the training of pelvic floor muscles.

The incontinence symptom severity index (ISSI) is a tool used to assess the severity of urinary abnormalities in women. It is calculated by multiplying the total value of the two parameters described below and is then converted into a severity index of three or four levels. The range of scores is from a minimum of 0 to a maximum of 8, or 12 for the fourth level. The higher the score, the more severe the symptoms. The scale has two questions, with the first being: “How often is urine leakage experienced?”. The answers given correspond to the following scores: never = 0; less than once a month = 1; one to several times a month = 2; one to several times a week = 3; every day and/or night = 4. The second question is: “How much urine is lost each time?”. The answer given corresponds to the following scores: a few drops = 1; a little = 2; more = 3. The severity index is then calculated as: (points for frequency) $\times$ (points for amount). The ISSI is therefore: 1–2 = slight; 3–6 = moderate; 8–9 = severe; 12 = very severe [13].

2.2 Procedures

Women in group A were asked to evacuate their bladder before the treatment session and to then lie supine on a PEMF bed while wearing light cotton clothes. Any metal objects and earpieces were removed and the subject was covered by a cotton sheet. The PEMF solenoid was adjusted to be located over the pelvis.

An automatic PMT Quattro PRO device (ASA sri, Arcugnano, Italy) was used for magnetic therapy. This consists of a control pannel, motorized bed and two solenoids (52 cm in diameter for the stand and 80 cm in diameter for the bed). The control panel was connected to an electrical mains supply of 230v $\pm$ 10%.

The standard treatment protocol was application of intermittent low-frequency stimulation (15 Hz) for 10 minutes followed by rest (no stimulation) for 2 minutes and then intermittent high-frequency stimulation (40 Hz) for 10 minutes. This treatment was applied twice a week for 8 weeks [14,15]. For the pelvic floor exercises, each patient was asked to lie in the crook position with the knees apart to avoid compensation by abdomen, glutei and hip adductors muscles. The exercises consisted of contraction and squeezing of the pelvic floor muscle for 10 seconds, followed by relaxation for 20 seconds and then resting for two minutes. The training lasted for 20 minutes and the procedure was repeated every other day for 8 weeks.

All women were advised to perform pelvic floor exercises regularly at home in the morning and before going to bed. They were asked to contract their pelvic floor muscles for 10 seconds followed by relaxation for 20 seconds and then rest for two minutes. This home training session should last for 20 minutes. Women were also advised to avoid constipation and straining, to treat the cause of any chronic cough or infection of the urethra or bladder, to stop smoking, eat a healthy diet and maintain normal body weight.

3. Outcome measures

The primary outcome measure was the strength of pelvic floor muscles as measured by perineometer. The secondary outcome measure was the severity of urinary incontinence as measured by the ISSI before and after 12 sessions of treatment.

4. Sample size calculation

To avoid a type II error, preliminary power analysis [power (1-α error P) = 0.90, $\alpha = 0.05$, effect size = 1.05405] determined that a sample size of 40 (two groups of 20 subjects each) was appropriate for this study. The effect size was calculated according to an earlier pilot study on 12 subjects (6 in each group) that used perineometer measurement as a primary outcome. The power analysis was performed by G*Power 3.1.9.2 software (Heinrich-Heine-Universität Düsseldorf in Germany) using *t*-test family and the statistical test difference between two independent means (two groups).

5. Statistical analysis

Statistical analysis was performed using SPSS for windows, version 26 (SPSS, Inc., Chicago, IL, USA). Prior to final analysis, the data were screened for normality assumption and the incidence of extreme scores. This was done as a prerequisite to parametric calculations on the analysis of difference. Descriptive analysis using histograms with a normal distribution curve and normality testing using the Shapiro-Wilk test showed the data for age, BMI and perineometer in both groups was not normally distributed. The Mann-Whitney U test and the Wilcoxon Signed Rank Test were therefore used to compare variables of interest in the different test groups (between groups) and measuring periods (within a group), respectively, for each dependent variable.

Comparison of nominal variables between the two groups was done by Chi-square test, with the Alpha level set to 0.05.

6. Results

The final statistical analysis included 40 patients, with 20 in group A (PEMF treatment) and 20 in group B. At baseline, there were no significant differences between the two groups with regard to age, BMI, level of education, parity or occupation (Table 1).

6.1 Pelvic floor muscle strength (perineometer measurements)

Prior to treatment, Mann-Whitney U test showed no significant difference ($p > 0.05$) in the mean perineometer value between groups A and B (Table 2). After treatment, group A showed a significantly higher mean perineometer value compared to group B. Moreover, both groups showed a statistically significant improvement following treatment.

6.2 Incontinence symptom severity index (ISSI)

Mann-Whitney U test revealed no significant difference in ISSI measures between groups A and B prior to any treatment (Table 2). However, group A showed a significantly lower mean ISSI after treatment compared to group B. Moreover, both groups showed significant improvement after treatment.

7. Discussion

Mixed incontinence is a critical healthcare issue with important personal, family and economic impacts. Its incidence is likely to increase as the elderly population continues to increase in number. The incidence of mixed incontinence is currently one in three women [2,16].

SUI is more likely to occur after childbirth, especially if the baby is delivered vaginally. This is because the pelvic floor muscles can expand, weaken, or be injured, causing a lack of bladder/urethral support and bladder leakage [13].

Surgical repair of SUI may not be successful and could lead to complications such as infection and delayed wound healing. PEMF on the other hand is a noninvasive technique that can be used to manage such conditions. Patients do not need to undress for this procedure because the magnetic field goes through clothing. PEMF has previously been investigated for its ability to activate striated urethral sphincters and to cause a short-term decrease in the activity of neurogenic and idiopathic detrusor. Magnetic stimulation has traditionally been used as a single pulse or else in a repetitive manner if there is overheating of the coil [17].

Table 1. Patient demographic data for groups A and B.

Qualitative variables		Group A	Group B	*p*-value
		frequency, %	frequency, %	
Age in years (mean ± SD)		(46.6 ± 6.99)	(46.3 ± 5.77)	0.918
BMI (mean ± SD)		(28.54 ± 0.92)	(27.84 ± 1.47)	0.218
Level of education	Read and write	2, 10	0, 0	0.296
	Basic	11, 55	14, 70	
	High	7, 35	6, 30	
Parity	Multipara	18, 90	17, 85	0.633
	Primipara	2, 10	3, 15	
Occupation	Housewife	17, 85	17, 85	1.000
	Working	3, 15	3, 15	

Table 2. Comparison of the outcome variables pre- and post-treatment between groups A and B.

	Treatment	Group A	Group B	*p*-value (between groups)
		mean ± SD (median)	mean ± SD (median)	
Perineometer	before	35.65 ± 9.33 (34.5)	32.35 ± 8.70 (29.5)	0.253
	after	46.85 ± 8.96 (46.5)	36.45 ± 9.09 (33.5)	0.001*
	p-value (within group)	0.000085*	0.000124*	
ISSI	before	4.65 ± 1.18 (5)	4.85 ± 1.27 (5)	0.461
	after	1.6 ± 1.09 (1.5)	3.25 ± 1.41 (3)	0.001*
	p-value (within group)	0.000074*	0.000092*	

*Denotes statistically significant at $p < 0.05$.

PEMF is a type of electromagnetic field at the lower end of the electromagnetic spectrum that has frequencies ranging from 6 to 500 Hz. It emits non-ionizing radiation that directs a sequence of magnetic pulses through the medium of biological tissue, each causing a tiny electrical signal that encourages cellular healing. The radiation has a non-thermal effect on biological targets [18].

PEMF was approved for use by the United States Food and Drug Administration in 1998. The pulsed magnetic fields are generated by an electrified coil that induces flow of ions to form eddy currents when the excitable tissue is exposed to a magnetic field with sufficient intensity. Therefore, magnetic stimulation depolarizes the motor nerve to produce an action potential that ultimately triggers muscle contractions [19].

Shamliyan *et al*. [20] reported that a magnetic field could activate the pudendal nerve and thus stimulate pelvic floor muscles. The stimulation of these muscles can improve urethral closure and thus treat SUI.

Ross *et al*. [21] reported that PEMF can penetrate deep into tissues and act at the cellular level, inducing changes to cell proliferation and differentiation, DNA synthesis and RNA transcription, protein phosphorylation, microvesicle motility, ATP production, activation of antioxidant enzyme and hormone secretion.

PEMF has proven to be a viable therapeutic option for UUI and/or SUI, as well as for overactive bladder syndrome caused by neurogenic detrusor overactivity. Its non-invasive nature and exceptional safety and tolerability are the main benefits of this treatment. PEMF can also affect local blood flow and other parameters, with nerves thought to be particularly sensitive. Stimulation by PEMF activates the efferent neurons and motor endplates of the pelvic floor muscle, resulting in increased muscular strength and endurance. It may also affect the rate at which the somatic nerve fires, thus impacting the pelvic musculature and sphincter tone [22].

PEMF has been shown to decrease the micturition reflex by inhibiting detrusor activity through multiple pathways. As the afferent branches of limb muscle nerves prevent voiding during fight-or-flight responses and afferent anorectal nerve branches prevent voiding during defecation, increased activity of the urethral sphincter induces relaxation of the detrusor muscle in response to bladder filling. The activity of the sympathetic nervous system also increases in response to bladder filling [23].

Fergany *et al*. [24] published a preliminary investigation in 1996 that found PEMF might decrease unstable detrusor contractions in women. PEMF could thus be a more acceptable and convenient form of neuromodulation and a more efficient method of electrical stimulation via implanted electrodes.

PEMF therapies can therefore be used to treat the source of dysfunction in a noninvasive, safe, and simple way [25].

The results of the present study agree with those of Bakar *et al*. [26] who showed that urinary symptoms and incontinence times improved after PEMF therapy. Yamanishi *et al*. [27] also reported that magnetic stimulation of the pelvic floor twice per week for 5 weeks significantly decreased stress urinary incontinence.

However, the results of the present study do not concur with those of Petra *et al*. [28] who reported that magnetic innervation therapy did not improve pelvic floor function.

The results of this study also agree with those of Bo *et al*. [29] and Hay *et al*. [30] who reported that pelvic floor training is an effective method for the treatment of SUI. In these studies, women were taught to pre-contract their pelvic floor muscles before and during increases in intra-abdominal pressure in order to avoid loss of urine, as well as to perform strengthening exercises. Soni *et al*. [31] also demonstrated that kegel exercise training increased the strength and endurance of pelvic floor muscles.

8. Conclusions

PEMF is an effective therapeutic modality for the treatment of women with mixed incontinence. Moreover, it is a painless and non-invasive method. The addition of PEMF to pelvic floor exercises is also recommended for the strengthening of pelvic floor muscles.

Author contributions

EAE and MAM collected the data design the procedure, and LAF wrote the manuscript. All authors shared in editing and editorial comments in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the ethics committee of the Faculty of Physical Therapy, KFS El Sheikh University (No.: P.T./WH/7/2021/11).

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Conflict of interest

The authors declare no conflict of interest.

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