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Effect of Long Term Pulsed Electromagnetic Field on Postmenopausal Stress Urinary Incontinence

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Abstract: Pulsed electromagnetic therapy is used to activate the pudendal nerve, which then activates the pelvic floor musculature, which is supposed to increase urethral closure and improve the stress urinary incontinence (SUI). Aim of the study: was to detect the long-term efficacy of pulsed electromagnetic therapy on post-menopausal SUI. Subjects and Methods: Forty postmenopausal females complaining from mild or moderate degree of SUI. They were recruited randomly from outpatient clinic of gynecological department in Al-Mataria teaching hospital, Egypt. Their ages ranged from 50 to 60 years old. The BMI of the patients was not exceeding 35 Kg/m^2. They were multipara. Their deliveries were normal vaginal delivery. All women were treated by pulsed electromagnetic field 2 sessions/ week for 8 weeks. The vaginal squeeze pressure and symptoms of SUI were assessed pre-magnetic therapy, post magnetic therapy at the end of 8 weeks, follow up at 3, 6& 12 months by biofeedback (Myomed 632v) and (UDI-6) respectively. Results: The vaginal squeeze pressure was significantly increased (p= 0.001), and UDI-6 was significantly decreased (p= 0.001), at post magnetic therapy, follow up at 3, 6& 12 months when compared with their corresponding values measured pre-magnetic therapy. There was no significant difference (p> 0.05) between post magnetic therapy measurements compared at different time assessment at 3, 6& 12 months. Conclusion: The encouraging results of our study supported that PEMF has long -term effect as a unique therapeutic modality for the treatment of postmenopausal SUI.
Keywords: Pulsed electromagnetic field, Postmenopausal, Stress urinary incontinence.

1 Introduction

Stress urinary incontinence (SUI), is the involuntary leakage of urine that occurs when there is an increase in intra-abdominal pressure as a result of coughing, sneezing, exercising, or lifting heavy objects. It is considered a very prevalent medical problem among postmenopausal women [1].

Although the specific process is unknown, it is thought that a drop-in estrogen levels in postmenopausal women causes atrophy of the urogenital part and urinary mucosa, as well as a shortening of the mucosal vascular network of urethra, causing hypersensitivity and urinary incontinence [2].

The pelvic floor muscle (PFM) supports the abdominopelvic organs and forms the basis of the abdominopelvic cavity. PFM is hypothesized to play an important role in the generation, and maintenance of intra-abdominal pressure, as well as urine continence. It is a strong correlation between increase in PFM strength and improvements in stress urinary incontinence. PFM treatment for SUI is based on the theory that a forceful contraction of the muscle clamps the urethra, increasing urethral pressure when there is an increase in intra-abdominal pressure [3].

Magnetic field creates electrical activity that depolarizes nerves and promotes contractility of PFM, according to law of Faraday for magnetic induction. Stimulation of motor nerve fibers and plates of motor ends on a regular basis will likely to increase muscle strength and endurance [4].

Electromagnetic therapy is a new technique for treatment urinary incontinence that involves sending a train of current pulses through one or more magnetic coils to induce a train of magnetic flux pulses which then induces an eddy current within the body, stimulating a group of PFM, the pudendal nerve and the external-urethral sphincter [5,6].

Surgery is not a preferred therapeutic choice due to the risks connected with intrusive operations, such as pelvic pain and urination issues. Magnetic stimulation (MS) is a viable therapeutic option for SUI, according to the 2017

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European Association of Urology guidelines for UI therapy **[**7**].**

Because of the growing geriatric population and the rising prevalence of SUI with age, the problem of SUI is becoming more prevalent. The kind and severity of SUI, as well as comorbidities, play a big role in deciding whether to go conservative or surgery. **[**8**].**

Pulsed magnetic stimulation is a noninvasive SUI therapy option with diverse physical, social and psychological elements of QoL. There was notably physical activities improvement, in both the short and long term. those enhanced QoL allows females to be more active with little stress **[**9**].**

Pulsed magnetic stimulation does not necessitate the use of a probe. It has a benefit of that magnetic field can penetrate bodily tissues without causing obvious changes. It goes through clothing without interruption, so the patient does not need to undress **[**4**].** So, this trial was done to add information about efficacy of short and long term pulsed electromagnetic on post-menopausal stress urinary incontinence, it could contribute to the field of physical therapy and patients suffering from SUI post menopause.

2 Subjects and Methods

Forty postmenopausal females complaining from mild or moderate degree of stress urinary incontinence symptoms (SUI) shared in this trial. They were recruited randomly from the Outpatient Clinic of Gynecological Department at Al-Mataria teaching hospital, Egypt. Ranging in ages from 50 to 60 years old. The BMI of the patients was not exceeding 35 Kg/m^2. They were multipara through normal vaginal delivery. Women with cardiac abnormalities, recurrent urinary tract infections, hypertension, diabetes mellitus, intra uterine device and previous surgical procedures such as hysterectomy were excluded from the trial. It was conducted under the acceptance of ethical committee NO:P.T.REC/012/002821 Faculty of Physical Therapy, Cairo University.

Instruments:

I) Evaluation Instruments:

- Recording data sheet: All data and information of each patient including name, age, height, weight and BMI were recorded in a recording data sheet.
- Standard weight/Height scale: For measuring weight & height to measure (BMI**)**.
- Biofeedback (Myomed 632v): For measuring vaginal squeeze pressure pre-magnetic, post magnetic therapy, at the end of 8 weeks, follow up at 3, 6& 12 months. It is manufactured by Enraf-Nonius B.V. with serial number 12.509. It is sensory translated with visual feedback.
- Urogenital Distress Inventory Questionnaire- (Short Form): For assessment the degree to which symptoms associated with SUI are troubling. It was used pre-magnetic, post magnetic therapy, at the end of 8 weeks, follow up at 3, 6& 12 months.

- **II- Therapeutic instruments:**

Electromagnetic device: Health wave's generator (Manufactured with Simeds S.r.l. by Machiavelli, Italy, with serial number “11492”.) with two separate emission channels and asynchronous operation was employed, along with 100 saved and storable programs that could be altered by the user (intensity, frequency and phase time). The different associated applicators are recognized automatically. Magnetic field strength up to "100" Gauss and output frequency from (1 – 100) Hertz are programmable. Waveform with a positive semi-sinusoidal component. The machine has a graphic display, multi-function control with encoder, and selection via a (MENU-SUBMENU), making it simple and straightforward to operate

Procedures:

I- Evaluation procedure

- BMI assessment: Weight & height was measured to know BMI through the equation: BMI= $weight/height^2$ (Kg/m^2).

- Vaginal squeeze pressure: The patient was in the (lithotomy - position), with a soft pillow behind her head and little cushions under her lower back and hips. The vaginal catheter was then attached to a vaginal pressure sensor that was placed into the vagina. A syringe in the vaginal catheter was used to expand it. She was requested to squeeze strongly to do (3) maximum (PFMs) contractions maintain each for (10) sec with (10) sec rest interval, then the mean of the (3) peak measurements obtained from the (3) tests to build up the baseline and follow up scores were recorded.

Urogenital Distress Inventory Questionnaire - Short Form (UDI-6): It is related to symptoms associated with lower urinary tract dysfunction especially SUI and it has 6 items: 1-urination frequency, 2-Leakage associated with feeling of urgency, 3-Leakage associated with activity, 4-Sneezing or Coughing little amounts of urine, 5-Emptying bladder with difficulty, and 6-Discomfort in the genital area or lower abdominal.Obtain the mean values of all the answered items then multiply by 25. Scores are turned to a possible range of 0-100. Higher scores mean more symptom distress. An “A-grade” recommendation was given to this scale by the International Consultation of Incontinence because published data indicate that the scale is valid, reliable, and responsive to change following standard psychometric testing.

2-Therapeutic procedures:

- **Pulsed electromagnetic therapy:** Ask the women to evacuate her bladder before the treatment session to be relaxed then assume a comfortable supine lying position while wearing light cotton clothes, removing any metals and ear piece if present and was covered by a cotton sheet. The appliance was connected electrical main supplying (230 V + 10 %). The solenoid was adjusted to be over affected parts of the body (pelvic region). The treatment session consists of two phases, (10) minutes at (10) Hertz and (10) minutes at (50) Hertz with a rest period of (3) minutes in between, for a total treatment time of about (20) minutes. All women were treated (2) times / week for (8) weeks [10].
- **General advice:** Perform pelvic floor exercises regularly. Avoid constipation and straining. Treat the cause of any chronic cough and infection of urethra or bladder. Stop smoking. Maintain a healthy weight. Drinking sufficient amounts of healthy fluids (water) and decrease the caffeine intake. Decrease the amount of acidic and spicy foods.

3 Results and Discussion

Forty postmenopausal females with mean age (54.43 ± 3.26 yrs) participated in this study. Their height ranged from 155.0 to 172.0 cm (161.80 ± 4.59 cm) while their weights ranged from 61.0 to 96.0 kg (80.08 ± 8.19 kg). Their BMI ranged from 26.50 to 34.70 kg/m^2 (30.80 ± 2.15 kg/m^2) (Table 1).

Repeated measures ANOVA test revealed a statistically significant difference between vaginal squeeze pressure values measured pre-magnetic therapy and different times of measurement (Wilks' Lambda= 0.118, F value = 67.198 and p value= 0.001). There were significant differences (p=0.001) at all the post treatment assessments compared to the pre-treatment values. Also, there was an improvement of the vaginal squeeze pressure compared to the pretreatment values, the increased noted were (20.34%,19.81%, 19.25%, 16.39%) post 8 weeks, follow up at 3, 6& 12 months respectively, (Table 2).

Table 1: Descriptive data of general patients' characteristics

	No.	Minimum	Maximum	Median	Mean	SD
Age	40	50.00	60.00	55.00	54.53	3.26
Height	40	155.00	172.00	160.00	161.80	4.59
Weight	40	61.00	96.00	80.00	80.08	8.19
BMI	40	26.50	34.70	30.70	30.80	2.15

Table 2: Mean values of vaginal squeeze pressure measured at pre, post 8 weeks, and follow up at 3, 6& 12 months

	Pre	Post 8 weeks	3 months follow up	6 months follow up	12 months follow up	F value	P value
Mean ± SD	26.60 ± 11.46	32.01 ± 11.76	31.87± 11.89	31.72± 11.94	30.96 ± 12.14	67.198	0.001*
Mean difference	----	5.41	5.27	5.12	4.36		
% change	----	20.34 ↑↑	19.81 ↑↑	19.25 ↑↑	16.39 ↑↑		
p value vs pre #	----	0.001 (S)	0.001 (S)	0.001 (S)	0.001 (S)		

F value= Repeated measures ANOVA test. S= p≤ 0.05= significant.

Repeated measures ANOVA test revealed no statistically significant difference between post magnetic therapy value and its corresponding values measured post magnetic therapy by 3, 6& 12 months (Wilks' Lambda= 0.833, F value= 2.465 and p value= 0.077) (Table 3).

Friedman ANOVA test revealed a statistically significant difference between UDI-6 values measured pre-magnetic therapy and different times of measurement (Chi square value= 116.725 and p value= 0.001).

There were significant differences (p=0.001) at all the post treatment assessments compared to the pre-treatment values. Also, there was a reduction of the UDI-6 compared to the pretreatment values, the decreased noted were (21.04%, 20.92%, 22.4%, 20.51%) post 8 weeks, follow up at 3, 6& 12 months respectively, (Table 4).

Table 3: Comparison between mean values of vaginal squeeze pressure in post magnetic and follow up at 3, 6& 12 months

	Post 8 weeks	**3 months follow up**	**6 months follow up**	**12 months follow up**	**F value**	**P value**
Mean ± SD	32.01 ± 11.76	31.87 ± 11.89	31.72 ± 11.94	30.96 ± 12.14	2.465	0.077 (NS)

Table 4: Mean values of UDI-6 measured at pre-magnetic therapy and its corresponding values measured post 8 weeks and follow up at 3, 6& 12 months

	Pre	**Post 8 weeks**	**3 months follow up**	**6 months follow up**	**12 months follow up**	**χ^2 value**	**P value**
Mean ± SD	39.11 ± 9.90	30.88 ± 9.43	30.93 ± 9.52	30.35 ± 9.68	31.09 ± 9.49	136.607	0.001*
Mean difference	----	8.23	8.18	8.76	8.02		
% change	----	21.04 ↓↓	20.92 ↓↓	22.4 ↓↓	20.51 ↓↓		
p value vs before #	----	0.001 (S)	0.001 (S)	0.001 (S)	0.001 (S)		

χ^2 value= Chi-Square test. S= p≤ 0.05= significant.

Friedman ANOVA test revealed no statistically significant difference between UDI-6 values measured at post magnetic therapy value and its corresponding values at 3, 6, 12 months (Chi square value= 2.132 and p value= 0.546), (Table 5).

Table 5: Comparison between values of UDI-6 measured at post magnetic therapy and its corresponding values measured at 3, 6& 12 months

	Post 8 weeks	**3 months follow up**	**6 months follow up**	**12 months follow up**	**χ^2 value**	**P value**
Mean ± SD	30.88 ± 9.43	30.93 ± 9.52	30.35 ± 9.68	31.09 ± 9.49	2.132	0.546 (NS)

SUI is a persistent and debilitating disorder in that urine which is lost involuntarily as a result of effort, physical activity, sneezing, or coughing **[**11**].**

Following menopause, ovarian function declines, resulting in estrogen insufficiency. Incontinence is caused by hormonal changes such as urethral mucosa thinning, decrease of urethral closure pressure, bladder dysfunction, sphincter dysfunction, or a combination of both [12].

The US food and drug administration accepted that pulsed magnetic field as a noninvasive approach for SUI since 1998. Its advantage as females can get therapy while clothed **[**13**].**

Homogeneous pulsed magnetic fields are generated by coil positioned under the surface of the magnetic device. The coil provides a powerful electromagnetic field that may penetrate deep into tissue and even into bones when used with large electric currents. The changing magnetic field causes a flow of monocles, which propagates electrical currents. Membrane depolarization is ensured by a voltage gradient. A substantial enough membrane depolarization causes a considerable action potential to form in the nerve tissues. This causes pelvic floor nerve stimulation and PFM contractions **[**14**].**

The results of this trial agreed with **Lim et al.,** who investigated the efficacy of magnetic stimulation (MS) on (QoL) in female with SUI and found that pulsed magnetic stimulation improved physical, social, and psychological aspects of quality of life in both the short and long term. At two months and one year after therapy, PMS is beneficial in reducing SUI symptoms **[**9**]**.

MS is a non- invasive, highly effective, painless and simple to administer as an outpatient therapy treatment for SUI **[**15, 16**].**

The findings of this study corroborated those of **Bakar et al.,** that discovered urine symptoms and incontinence conditions improved post pulsed electromagnetic field (PEMF) sessions. The findings of the test of pad revealed decrease in urine leakage. The values of (EMG) improved. After the treatment, the (I-QoL), (UDI-6) and (VAS) scores decreased, indicating that PEMF may be used as an alternate, noninvasive, and painless therapy approach for treating (SUI) **[**17**].**

According to **Fujishiro et al.,** urodynamic studies showed an obvious increasing in maximum closure pressure of the urethra and an increase in mean capacity of bladder after repetitive treatment of magnetic field of the roots sacral nerves **[**18**]. Galloway et al,** found that PEMF administered 2 times / week for 6 weeks alleviated the symptoms of (SUI) and this effect was established for 3months **[**19**]. Yamanishi et al.,** found that after PEMF treatment for 10 weeks, International Consultation on Incontinence Modular Questionnaire and Quality of Life (ICIQ-QOL) values & 24-hour test pad reduced when compared with baseline in the study group **[**20**].**

Lo et al., observed that after 9 weeks of MS, both the Urogenital Distress Inventory and Incontinence Impact Questionnaire total scores improved significantly **[**21**]. Sun et al.,** found favorable results after PEMF resulting in improvements in (1h pad test), (UDI-6) and (IIQ-7) all of that exhibited improvement at the 12-month follow-up **[**22**].**

Tsai et al., supported the findings of our study. When compared to the control group in his experiment, the study group showed reductions in (UDI-6) and The Overactive Bladder Questionnaire (OAB-q) values post-treatment and at follow-up visits (4.5 months). Improvements in bladder capacity, functional length of urethra, and transmission pressure ratio were also seen following therapy **[**23**].**

Doganay et al., conducted a trial with a longer follow up period (6 months, 1, 2, 3 years) and assessed PEMF as a therapy for SUI using a 5day voiding diary, 1h test pad. These measures showed statistical improvement up to the first-year post-treatment, then gradually declined until they were near to the baseline by the third-year post PEMF treatment **[**24**].**

Samuels et al., discovered that 61 out of 75 patients (81.33 percent) demonstrated a substantial reduction in symptoms after the (16) MS sessions. The International Consultation on Incontinence Modular Questionnaire-Short Form ICIQ-SF score increased by 49.93% on average after the sixth session, and it improved to 64.42% during the follow-up. After the sixth treatment, the average reduction of absorbent pads was 43.80%, and after three months, it was 53.68%, with over 70 %of patients (30 out of 43) reporting a drop in the number of used pads. The improvement in (ICIQ-SF) score and the decrease in using pad were found to have a highly significant medium correlate at the follow-up which was at three months [25**].**

Weber-Rajek et al., who made a comparison between the results at the beginning and end of 4 weeks of treatment with MS and showed a statistically significant improvement in urinary incontinence severity using (The Revised Urinary Incontinence Scale), and perceived self-efficacy assessment (General Self-Efficacy Scale) **[**26**].**

The current results of our study also supported with those of **Hoscan et al.,** who reported that the effects of MS lasted for about a year following treatment **[**27**].** The current findings, on the other hand, contradicted with those of **Petra et al.,** who investigated the effects of magnetic stimulation in the treatment of pelvic floor dysfunction and found that magnetic innervation therapy had no influence on pelvic floor function. This contradiction may contribute to their sample included patients of SUI (only nine out of 74) were treated for two episodes of 10 min at 50Hz, with an interval of 1min. **[**28**].**

Furthermore, **Groenendijk et al**., claimed that PEMF had no efficacy on (PFM). There was no substantial effect of MS treatment in terms of quality of life, or a link between urodynamic values and clinical success. Urodynamic indicators improved with treatment; however, this had little bearing on the clinical outcome. the contradiction is contributed to the small sample (16 patients) with different urinary incontinence (UI) including with urge, stress and mixed urinary incontinence, while the current study included bigger sample with unified type of UI. **[**29**].**

Culligan et al., investigated the effect of MS on (PFM) strength (as determined by perineometer) in primiparous females. Primigravid patients were randomized to receive either active or sham MS postpartum treatments for 8 weeks. The main outcome measure was pelvic muscle strength measured by perineometer at baseline (mid-trimester) and 6 weeks (before treatments), then 14 weeks, 6 months, and 12 months postpartum. Fifty-one patients enrolled and 18 were lost to attrition. They found no change between who received study or controlled MS at early post-partum time **[**30**].** This disagreement may be due to the impact of recent pregnancy and labour on PFM strength, while the current sample were in different age category.

4 Conclusions

The encouraging results of our study supported that PEMF has long -term effect as a unique therapeutic modality for the treatment of postmenopausal SUI.

Conflict of interest:

The authors confirm that this article content has no conflict of interest.

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