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Impact of pulsed electromagnetic on chronic pelvic inflammatory disease: A randomized controlled trial

*Wpływ pulsującego pola elektromagnetycznego na przewlekłe zapalenie miednicy:
Randomizowane badanie kontrolowane*

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Abstract

Purpose. Pelvic inflammatory disease (PID) is an infection-induced inflammation of the female upper reproductive tract some cases not respond to medical treatment, the aim of the study to detect the effect of pulsed electromagnetic (PEMF) in treatment of chronic pelvic inflammatory disease. Materials and Methods. this study was designed as single blind randomized controlled trial. Forty females complain from PID, their age ranged from (20-40) years and their body mass index (BMI) not exceeds 30 kg/m², they and were randomly assigned into 2 equal groups: Study group (A) received oral antibiotic (doxycycline 100 mg) twice daily for 7 days in addition to PEMF for 1 hour, 3 times per week for 12 sessions with 50 Hz in frequency and 60 G in intensity. Control group (B) received routine medical treatment by oral antibiotic (doxycycline 100 mg) twice daily for 7 days. Both groups were assessed by present pain intensity scale, estimation of C-reactive protein and ESR level in blood before the treatment and after 12 sessions of PEMF. Results. There were significant differences in pain scores presented by Mean Difference (MD) and 95% Confidence Interval (CI) (MD 2; 95%CI 1.8 to 2.21), ESR (MD 16.75; 95%CI 13.973 to 19.52) and CRP (MD 35.8; 95%CI 31.97 to 39.63) between the both groups. The significant improvement from pretreatment to post treatment, was seen in all dependent variables at study group ($p < 0.05$) and in pain severity and CRP in control group. Conclusion. Pulsed electromagnetic yields improvement in pain and decrease in inflammation measured by decrease inflammatory markers in the treatment of pelvic inflammatory disease.

Key words:

Pelvic inflammatory disease, Pulsed electromagnetic field, ESR, C-reactive protein.

Streszczenie

Cel. Choroba zapalna miednicy (PID) jest wywołanym infekcją zapaleniem górnych dróg rodnych u kobiet. W niektórych przypadkach choroba nie reaguje na leczenie. Celem niniejszego badania było wykrycie wpływu pulsacyjnego pola elektromagnetycznego (PEMF) w leczeniu przewlekłej choroby zapalnej miednicy. Materiały i metody. Badanie zostało zaprojektowane jako pojedyncza ślepa, randomizowana próba kontrolowana. Czterdzieści kobiet chorych na PID w wieku od 20-40 lat; wskaźnik masy ciała (BMI) nie przekraczał 30 kg/m². Kobiety zostały losowo przydzielone do 2 równych grup: Grupa badana (A) otrzymywała doustny antybiotyk (doksycyklina 100 mg) dwa razy dziennie przez 7 dni oraz była poddawana działaniu pulsującego pola elektromagnetycznego przez 1 godzinę, 3 razy w tygodniu, 12 sesji z częstotliwością 50 Hz i intensywnością 60 G. Grupa kontrolna (B) została poddana rutynowemu leczeniu doustnymi antybiotykami (doksycyklina 100 mg) dwa razy dziennie przez 7 dni. Obie grupy oceniano za pomocą aktualnej skali natężenia bólu, oceny poziomu białka C-reaktywnego i OB we krwi przed leczeniem i po 12 sesjach pulsującego pola elektromagnetycznego. Wyniki. Wystąpiły istotne różnice w wynikach bólu przedstawionych jako średnia różnica (MD) i 95% przedział ufności (CI) (MD 2; 95% CI 1,8 do 2,21), OB (MD 16,75; 95% CI 13,973 do 19,52) i CRP (MD 35,8; 95% CI 31,97 do 39,63) w obu grupach. Istotną poprawę od momentu przed leczeniem zaobserwowano dla wszystkich zmiennych zależnych w grupie badanej ($p < 0,05$) oraz w nasileniu bólu i CRP w grupie kontrolnej. Wnioski. Pulsacyjne pole elektromagnetyczne powoduje poprawę w zakresie intensywności bólu i zmniejszenie stanu zapalnego mierzonego zmniejszeniem markerów stanu zapalnego w leczeniu chorób zapalnych miednicy.

Słowa kluczowe:

Choroba zapalna miednicy, pulsujące pole elektromagnetyczne, OB, białko C-reaktywne

Introduction

Pelvic inflammatory disease (PID) is a term that describes an infection of upper genital or reproductive tract that involve infection of the endometrium, the oviducts, the ovary, the uterine wall or peritoneum. PID is a common and morbid condition that affects about 8-11% of women in their reproductive period [1]. It results from bacterial infection including chlamydia trachomatis and Neisseria. The most common symptoms of PID are bilateral lower abdominal pain and tenderness with walking and coitus, abnormal vaginal discharge and rarely associated with irregular vaginal bleeding [2].

The usage of intrauterine device and vaginal douches allow ascending of microorganism through vagina, uterus and fallopian tubes [1]. Diagnosis of PID depend on clinical examination, the patient complain, abnormal vaginal or cervical discharge, measuring of body temperature and determining of serum leukocyte concentration or C - reactive protein or cervical swab [3]. Delayed treatment of PID lead to ectopic pregnancy increase six to ten fold in women, chronic pelvic pain increased fourfold and infertility occur in 40-60% of cases [4]. Patients with pelvic inflammatory disease (PID) are not routinely referred for physical therapy until the condition is found to be resistant to antibiotic therapy [5]. Physical therapy modalities as phnophoresis by bee venom and interferential have good effect in treatment of PID [6].

Pulsed electromagnetic wave (PEMF) therapies have advantages in their affordability in treatment of inflammation and decrease sensation of pain over both pharmaceuticals with less side effect. Other benefits include ready availability, ease of localized application, and indefinite shelf life [7]. Over the historical eras, the therapeutic effectiveness of PEMF is effective method in treatment of inflammation decrease edema. In addition; it has positive effects on cartilage healing [8]. The primary mechanism of action of PEMF-mediated analgesia hypothesized to involve promoting the reduction and, possibly, resolution of inflammation. [7] [8]. PEM is developing therapy for the treatment of both acute and chronic inflamma-

tion [9]. No study has yet detected the effect of PEMF in treatment of pelvic inflammatory diseases. Thus, the aim of this study was to investigate the effect of this modality in treating such cases.

Materials and methods

Study design

The study was designed as a randomized, single-blind, pre-post-test, controlled trial.

Participants

A convenient sample of Forty women were allocated from Outpatient Clinic of Gynecology Department at kafr elsheikh hospital diagnosed as having chronic pelvic inflammatory disease. This study was approved by ethical committee of Faculty of Physical Therapy Cairo University number P.T.REC/012/002194. They were assessed for their eligibility to share in the study, their age ranged from (20-40) years and their body mass index (BMI) not exceeds 30 kg/m², the cases were referred from gynecologist diagnosed as chronic pelvic inflammatory disease, They complained from a constant and diffuse lower abdominal pain radiating to lumber region with abnormal vaginal discharge, elevated inflammatory marker c- reactive protein and erythrocyte sedimentation rate (ESR) as well as they were not responded to medical treatment. Participant were excluded if they have benign or malignant tumor in pelvic region, uterine mass, active endometriosis, tubal occlusion diabetes, tubooverian abscess, hemorrhage as well as sacroiliac joint pain, Also, none of the patients was pregnant or using intra uterine contraceptive device.

Randomization

Participants were randomly assigned into two equal groups (group (A) and group (B) by a blinded and an independent physiotherapist who opened sealed envelopes that contained a computer generated randomization card. No subjects dropped out of the study after randomization (figure 1).

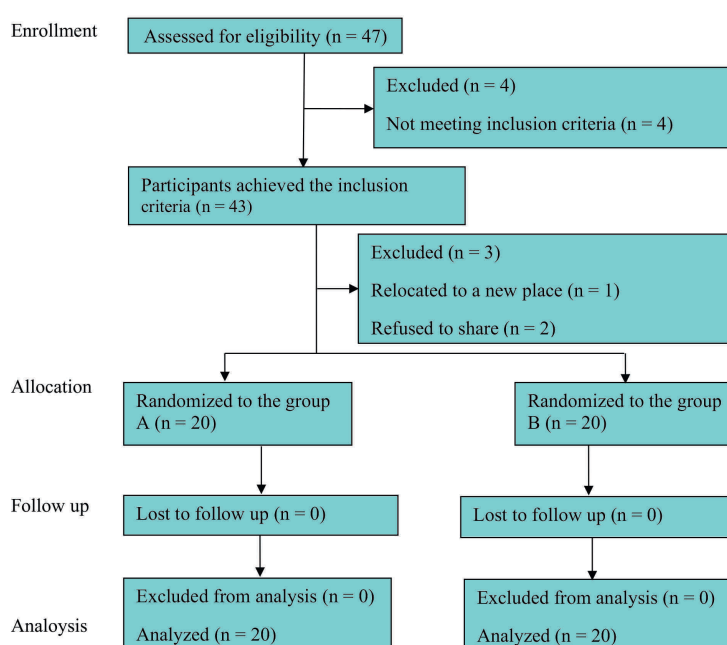


Figure 1. Flow chart of the participants during the trial

Intervention

After history taking, informed consent had been signed from each patient before starting in the study. The patient was randomly assigned into 2 group, group (A) received oral antibiotic (doxycycline 100 mg) twice daily for 7 days [10] in addition to PEMF (Fisiofield Mini, Italy, dir. 93/42/CEE, frequency 1–100 Hz and intensity of 1–100 G) application for 1 hour, 3 times per week for 12 sessions, the patient in this group were instructed to lay in a comfortable crock lying position with small pillows under her body curves. Then, one of the PEMF electrodes was applied on the suprapubic region and the other electrode under the lumbar region and they were fixed by long strap. The used parameters of PEMF were 50 Hz in frequency and 60 G in intensity.

Group (B) received routine medical treatment by oral antibiotic (doxycycline 100 mg) twice daily for 7 days.

Outcome measures

Assessment of pain intensity for each patient in both groups was performed before and after the end of treatment by using present pain intensity scale [11].

Lab investigation: estimation of the and C-reactive protein & ESR by five ml of blood drained from antecubital vein from each patient before and after end of treatment to estimate C-reactive protein by Latex agglutination method and Westergren method to estimate ESR.

Sample size and Statistical analysis

Test size estimation was performed preceding the investigation utilizing G*POWER statistical programming (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany) [F tests- MANOVA: Special effects and interaction, $\alpha = 0.05$, $\beta = 0.20$, Pillai V = 0.16, and effect size = 0.19] and revealed that the appropriate sample size for this study was N = 39]. This effect size calculated from pilot study on 10 participants (5 in each group) (figure 2).

All statistical measures were performed using the Statistical Package for Social Science (SPSS) program version 23 for windows. Prior to final analysis, data were screened for normality assumption, and presence of extreme scores. This exploration was done as a pre-requisite for parametric calculation of the analysis of difference and analysis of related measures. Descriptive analysis using histograms with the normal distribution curve showed that the data were normally distributed and didn't violate the parametric assumption for the pain, ESR and CRP. Additionally, testing for the homogeneity of covariance using Box's test revealed that there was no significant difference with p values of > 0.05 . Normality test of data using the Shapiro-Wilk test was used, that reflect the data was normally distributed for the pain, ESR and CRP. All these findings allowed the researchers to conduct parametric analysis. So, 2x2 mixed design MANOVA was used to compare the tested variables of interest at different tested groups and measuring periods. The alpha level was set at 0.05.

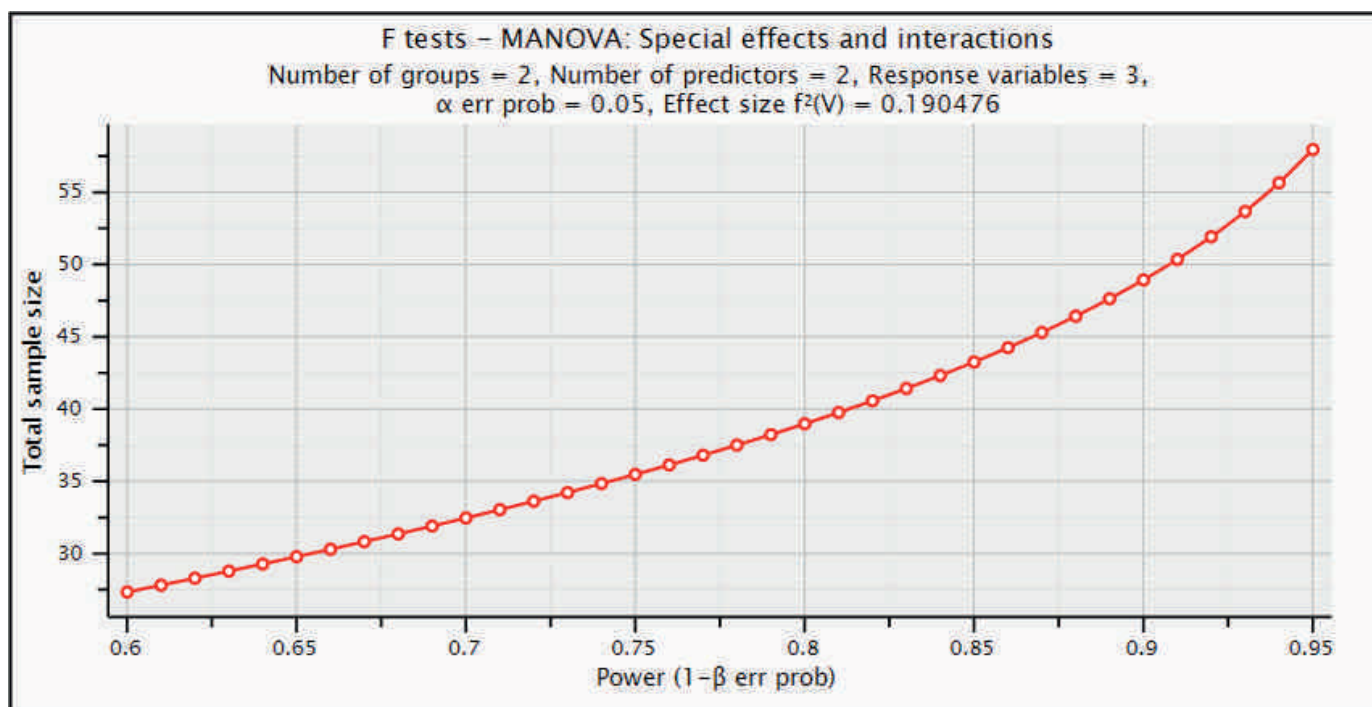


Figure 2. Plot of sample size calculation

Results

A total of 47 patients with chronic pelvic inflammatory disease were eligible for inclusion, and 40 were randomized to study intervention (fig 1).

The experimental group (A) of 20 patients who received oral antibiotic (doxycycline 100 mg) twice daily for 7 days in addition to PEMF application for 1 hour, 3 times per week for 12 sessions.

The control group (B) consisted of 20 patients who only received routine medical treatment by oral antibiotic (doxycycline 100 mg) twice daily for 7 days. All randomized patients completed the trial. The independent t-test revealed that there was no significant difference ($P > 0.05$) between subjects in both groups concerning age and BMI, (Table 1).

Table 1. Physical characteristics of participants in each group (Mean \pm SD)

General characteristics	Group A (Mean \pm SD)	Group B (Mean \pm SD)	p-value
Age (years)	29.53 \pm 3.48	30.133 \pm 2.99	0.362
BMI (kg/m ²)	24.3 \pm 3	25.26 \pm 2.64	0.61

SD: Standard deviation; p-value: Level of significance

Statistical analysis using mixed design MANOVA revealed that there were significant within subject effect ($F = 150.505$, $p = 0.0001$) and treatment*time effect ($F = 68.56$, $p = 0.0001^*$). As well as, there was significant between subject effect ($F = 11.303$, $p = 0.0001^*$). (Table 2 and 3) present descriptive statistic, Within and between groups differences at 95% CI for the effects of interventions for the all dependent variables. In the same context regarding within subject effect, the multiple pair-

wise comparison tests revealed that there was significant reduction ($p < 0.05$) in pain intensity and CRP at both groups while there was significant reduction ($p < 0.05$) in ESR at group A only in the post treatment condition compared with the pretreatment. Regarding between subject effects multiple pairwise comparisons revealed that there was significant difference of pain, ESR and CRP between both groups ($p < 0.05$) and this significant reduction in favor to study group.

Table 2. Descriptive statistics for the all dependent variables for both groups at different training periods

Variables	Study group (A)		Control group (B)	
	Pre	Post	Pre	Post
Pain Severity	3.3 \pm 0.65	0.85 \pm 0.74	3.2 \pm 0.69	2.75 \pm 0.63
ESR	28 \pm 11.08	8.8 \pm 4.03	26.45 \pm 10.78	24 \pm 9.96
CRP	57.6 \pm 12.67	9.9 \pm 4.02	50.4 \pm 19.31	38.5 \pm 13.53

Values of all dependent variables are expressed as mean \pm SD

Table 3. Within and between groups differences at 95% CI for the effects of interventions

Variables	Within groups		Between groups	
	Study group Mean difference (95% CI)	Control group Mean difference (95% CI)	Mean difference (95% CI)	MCID
Pain Severity	2.45 (2.139 to 2.761)*	0.45 (0.139 to 0.761)*	2 (1.8 to 2.21)*	0.271
ESR	19.2 (16.25 to 22.15)*	2.45 (-0.5 to 5.4)	16.75 (13.973 to 19.52)*	1.79
CRP	47.7 (42.12 to 53.28)*	11.9 (6.32 to 17.48)*	35.8 (31.97 to 39.63)*	2.47

CI: Confidence Interval, MCID: Minimal Clinically Important Difference, * the mean difference is significant at the 0.05 level

Adverse events

There are no adverse events occurred during the study.

Discussion

Pelvic inflammatory disease (PID) is an infection of female genital tract which represent major gynecological problem approximately 60% of this cases suffered later from infertility which cause a major social and psychological problems [2] the main cause of PID referred to infection of female's genital organs begin from vagina and spread to cervix and fallopian tubes, uterus and ovaries, PID may lead to ectopic pregnancy and chronic pelvic pain [12]. The medical treatment in some cases not produce improvement in addition to the side effects of an-

tiinflammatory and analgesic drugs on stomach, hepatic, renal, hematologic, gastrointestinal discomfort and central nervous system toxicity including indigestion, nausea, abdominal pain, constipation, diarrhea, vomiting, headache, dizziness, vertigo, visual disturbances as blurred vision [13].

The result of the study clear that, PEMF can improve pain measured by present pain intensity scales and decrease in inflammation measured by decrease in ESR and C-reactive protein $p < 0.05$. The result of the study agrees with Harper WL et al. [14], who suggested that PEMF has good effect in decrease pain and inflammation, The improvement in study group may be explained by Markov and Colbert [15], who stated that magnetic field therapy has analgesic characteristics by increasing pain

threshold, stimulating production of opioid peptides, anti-inflammatory, vasodilatation, and anti-edematous activity without side effects, and accompanied by activation of the anticoagulation system.

The current study agrees with Jorgensen, [16] who suggest electromagnetic fields generated by the ion magnetic inductor (PAPIMI-300) have been shown to relieve pelvic pain of gynaecological origin in humans. The effect of PEMF on inflammation explained by Moffett et al. [17] who suggest that PEMF treatment is followed by decrease in the expression of interleukin 1 beta and tumor necrosis factor alpha, as well as an increase blood oxygen, alkalinize bodily fluids, increase white blood cells, absorption of edema & hematoma and remove toxic materials from the wall of blood vessel or through effects on cellular calcium channels [18].

This study in line with Mohamed et al. [19, 20] who concluded that PEMF has good effect in decrease level of prostaglandin as a treatment of dysmenorrhea and providing a simple, safe, inexpensive and successful alternative therapy rather than pharmacological treatment

In the treatment of bacterial infections, antibiotics have proven to be very effective, but the way in which antibiotics are dosed can create a lag time between the administration of the drug and its absorption at the site of insult but the application of PEMF can be used on the site of pain or inflammation, decrease the growth rate of bacteria and penetrate even poorly vascularized tissue [21] Further, the beneficial effects of PEMF have been reported

to last up to 3 months or longer in human patients with chronic inflammatory/autoimmune disorders with no evidence of adverse effects [22, 23]. In addition to the PEMF therapies have few if any side effects and have a major advantage in their affordability over both pharmaceuticals and the cost of surgery. Other benefits include ready availability, ease of localized application, and indefinite shelf life [24].

Conclusion

The findings of the study may be limited by the assessment by lab investigation and pain intensity scale without cervical swap or laparoscope and lack of follow-up for PID in both groups for several months' after rehabilitation program to evaluate the long lasting effect, recommendations for future research are conducting the same study on a large sample size, use different frequencies. In conclusion this study shows that 12 sessions of PEMF fields improvement in pain and decrease in inflammation measured by decrease inflammatory markers in the treatment of pelvic inflammatory disease.

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