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Effect of pulsed electromagnetic field versus aerobic exercises on women with polycystic ovary syndrome: A single-blind randomized controlled trial

Effect of electromagnetic field on polycystic ovary syndrome

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Abstract

Aim: Polycystic ovarian syndrome (PCOS) produces symptoms in approximately 5% to 10% of women of reproductive age (12–45 years old). It is thought to be one of the leading causes of female infertility and the most frequent endocrine problem in women of reproductive age. This study was an attempt to compare the effect of pulsed electromagnetic field versus aerobic exercise on women with polycystic ovary syndrome. Material and Method: Thirty obese PCOS women participated in this study; their age ranged between 20 and 35 years. They were randomly and equally allocated to two groups: Group A which composed of 15 women who received PEMF and Group B which composed of 15 women who followed a program of aerobic exercises in the form of walking on the treadmill for 40min/session, all participants in both groups had 3 sessions/week for 12 weeks, in addition to their prescribed diet. Evaluations of both groups (A&B) were performed before and after the study by measuring their weight, body mass index (BMI), C-reactive protein (CRP), luteinizing hormone (LH)/ follicle stimulating hormone (FSH) ratio. Results: Statistical analysis revealed that there was a significant reduction ($p < 0.05$) in weight, BMI, CRP, and LH/ FSH ratio in the post- treatment condition compared with the pretreatment one in both groups. Regarding between-subject effects, there was a significant reduction ($p < 0.05$) in CRP and LH/FSH ratio in Group A compared with Group B, with no significant differences in weight and BMI between both groups ($p > 0.05$). Discussion: Pulsed electromagnetic field was more effective than aerobic exercise in reducing CRP and LH/FSH ratio in PCOS women with no difference in their effect on the body weight or the BMI.

Keywords

Pulsed Electromagnetic Field; Aerobic Exercise; Polycystic Ovarian Syndrome

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Introduction

Polycystic ovarian syndrome (PCOS) is a complex, heterogeneous disorder of undefined etiology; it is one of the most common female endocrine disorders. There is strong evidence that it can be classified as a genetic disease [1]. The definite pathophysiology and causes of PCOS are a complex, the hormonal imbalance may be due to hyperinsulinemia and hyperandrogenemia plus the patient lifestyle and genetic factors [2]. PCOS is a pro-inflammatory state. Data suggest that chronic low-grade inflammation leads to the development of the metabolic disorder and ovarian dysfunction occurs [3]. The status of chronic low-grade inflammation in PCOS has focused on the measurement of circulating C- reactive protein (CRP) [4]. CRP is considered to be the most reliable circulating marker in such a case [5].

The link between inflammation and obesity is a positive correlation between adipose mass and expression of the pro-inflammatory gene tumor necrosis factor-α (TNFα). The link between obesity and inflammation has been also illustrated by the increased plasma levels of several pro-inflammatory markers including cytokines and acute phase proteins like CRP in obese individuals. Many of the inflammatory markers found in plasma of obese individuals appear to originate from adipose tissue. These observations have led to the view that obesity is a state of chronic low-grade inflammation that is initiated by morphological changes in the adipose tissue [6].

In recent years, interest in magnetic field therapy has increased rapidly as research shows that it is a noninvasive, cost-effective modality and might be safer than drugs and surgical procedures for reduction of inflammation [7].

Every cell membrane carries an electromagnetic charge, and pulsed electromagnetic field (PEMFs) alters this charge by causing movement of ions across the cell membrane. Low- level PEMFs have been shown to exert an anti-inflammatory effect through the restoration of plasma membrane calcium ATPase activity [8]. PEMF devices can be attuned to certain vibrational frequencies and field strengths in order to stimulate hormones and growth factors [9].

Also aerobic exercise training was found to have a direct effect on inflammatory process as it reduces blood levels of leukocyte adhesion molecules, inhibits interactions between monocytes and endothelial cells, decreases the production of pro-inflammatory cytokines, decreases CRP levels and increases the production of anti-inflammatory cytokines by mononuclear cells, maintains balance between the production of pro-inflammatory and anti-inflammatory cytokines in skeletal muscles, improves antioxidative defenses [10]. An aerobic training program in obese women with PCOS leads to a significant reduction of body weight, body fat percentage, and waist circumference. Also, aerobic training leads to improvement in maximum oxygen consumption (VO_{2max}) as result of improvement of oxidative phosphorylation capacity of muscles, stroke volume of the heart and oxygen content of blood [11].

Exercise, diet and weight reduction are improving factors to ovulation and conception in PCOS. Often only 3 to 5 Kg weight loss will restore regular menstruation, ovulation, and fertility [12]. Unfortunately, the literature review was unable to identify any study comparing the effect of pulsed electromagnetic field versus aerobic exercise on polycystic ovarian women. Consequently, we conducted this study to compare their different effects on PCOs patients.

Material and Method

The study was designed as a prospective, randomized, single-blind, pre-test, post-test, controlled trial. Ethical approval was obtained from the institutional review board at the Faculty of physical therapy, Cairo University before study commencement. The study followed the Guidelines of the Declaration of Helsinki on the conduct of human research. The study was conducted between June 2017 and March 2018.

This study was carried out on thirty obese women diagnosed with a polycystic ovarian syndrome (PCOS) who were selected from Outpatient clinic of Cairo university hospitals, Egypt. They were enrolled and assessed for their eligibility to participate in the study. The age of the participants ranged from 20 to 35 years, their body mass index (BMI) ranged from 30 to 34.9 kg/m2. All participated women had amenorrhea (no menses in the last 6 months) or oligomenorrhea (less than four cycles in the last 6 months) and typical ultrasonographic presentation of PCOS of multiple sub-capsular follicles and thickened ovary as well as LH/FSH >2. The participants were excluded if they had specific disorders as hyperadrenalinemia, and androgen-secreting neoplasia, thyroid dysfunction, Cushing's syndrome, ovarian tumor and malignancy, the use of medications (known to affect the hypothalamic-pituitary-ovarian axis). Patients with other causes of chronic inflammation as osteoarthritis at the starting time as well as patients used anti-inflammatory drugs, hepatic diseases, Cardiac diseases, chest diseases, severe life-limiting illness (cancer, renal failure), diabetes and Obese class II and III, contraindication for PEMF as implanted device, pacemaker, malignancies, active tuberculosis, acute viral conditions, severe atherosclerosis, neurological diseases with seizure, hyperthyroidism and Viral infections. Written informed consent was obtained from all participants before the baseline evaluation. After a brief orientation session about the nature of the study and the tasks to be accomplished, they were randomly assigned into two equal groups: Group A and Group B by a blinded and an independent research assistant who opened sealed envelopes that contained a computer-generated randomization card. No subjects dropped out of the study after randomization. Participants were randomly assigned to one of two groups. Group A composed of 15 women who received PEMF 3 sessions/week for 12 weeks, and Group B which composed of 15 women, followed a program of aerobic exercises in the form of walking on the treadmill for 40 min/session, 3 sessions/week for 12 weeks, all patients in both groups follow a prescribed diet.

Pulsed electromagnetic field treatment sessions for Group A:

PEMF machine was applied by Health waves generator with two independent channels manufactured by Simeds S.r.l. via Machiavelli 10/a, Mogliano Veneto (TV), Italy) with serial number 11492, the operating voltage and frequency used are 230 V AC 50Hz and Magnetic field intensity from 10: 100 Gauss- Positive semi-sinusoidal waveform. Before starting each treatment session, each patient in the Group A was instructed to follow the rules and safety precautions of application PEMF. The patient was instructed to lie comfortably in supine lying position, then the two plates of magnetotherapy of 18*18 cm dimension, was placed over the lower lateral abdominal quadrant of the patient (RT and LT) below the level of umbilicus by 5cm on right and left side, then the magnetotherapy device was adjusted as described in Table 1, the total treatment session lasted for 30 minutes. The EMF sessions was applied 3 times/ weeks for 12 weeks, in addition to their prescribed diet.

Table 1. Parameters of electromagnetic therapy

PHASES	Intensity %	Frequency	Time
PHASE 1	90 %	2 Hz	5 min
PHASE 2	100 %	4 Hz	15 min
PHASE 3	80 %	Random	10 min

Exercise program for Group B

Before starting the exercise, complete explanation about what was going to be performed during the exercise session was given to each woman.

Aerobic exercise

Treadmill (Deluxe motorized treadmill 3 HRC) with model number 8618RHD and serial number 140910723 was used for performing aerobic exercises for women in Group B for 40 minutes/session, 3 sessions per week for 12 weeks. The Treadmill has the following specifications: Speed range (0.8 mph to 16 mph), elevation range (0% to 15%) and power (220v, 60Hz, 15 amp). The exercise on the treadmill was divided into 3 stages:

The first stage (Warming up): starts with 5 minutes at slow speed with zero inclination to enhance patient performance by facilitating circulatory adjustment and minimizing the formation of lactic acid and to decrease the risk of hypotension, musculoskeletal and cardiovascular complications.

The second stage (Active phase): The speed of the treadmill was increased gradually to achieve at least 70 % of maximum heart rate (HR max) for each woman. Duration gradually increased to 20 minutes.

The third stage (Cooling down or Recovery Period): At the end, the speed of the treadmill was gradually decreasing until it reached zero for 5 minutes to allow the heart rate to return nearly to the resting level.

All women in both groups A and B underwent the same diet guidelines during the study period for 12 weeks. This study recommended the hypocaloric diets which included high-carbohydrate (55% calories) and low fat (30% of calories) with average protein (15%) [13]. In order to determine the daily caloric requirement of each woman, firstly, the total daily energy requirement for each woman was calculated according to the Harris-Benedict formula [14]; [for women: BMR= 655+ (9.6*weight in kg) + (1.8*height in cm) - (4.7* age in years)], then multiply the result by the activity multiplier BMR * 1.2, 1.375, 1.55, 1.725 and 1.9 for sedentary, lightly active, moderately active, very active and extremely active; respectively. Then reduce a 500–1000 kcal/day of the calculated total daily energy requirement. This procedure was repeated at the beginning of each week according to each woman's new weight to determine her allowed caloric intake.

Outcome measures

The weight-height scale was used to measure the weight and height of each woman before and after the program. Then, the BMI was calculated by dividing weight by height squared (Kg/m^2). The scale was calibrated then each woman in both groups was placed over the scale. Weight and height were measured for each woman in both groups (A and B) before starting the study and at the end of the study (after 8 weeks).

Biochemical assays:

Blood samples were collected to measure the levels of the woman circulating LH/FSH ratio and CRP before and after the study (8 weeks). A sample of 5ml venous blood using a serum separator tube was taken from each woman in both groups (A and B) on the third day of the menstrual cycle. Laboratory analysis was performed to detect the level of LH, FSH, LH/FSH ratio and CRP in their blood. Samples were allowed to clot for one hour at room temperature, centrifuged for 10 minutes at 1000 g, using a clean pipette technique to Aliquot 2 ml of serum into labeled cryovials, and were immediately freezed. Serum LH and FSH concentration were measured using monoclonal antibodies and immunometric assay, Immulite; CRP was measured using NycoCard reader II.

Statistical analysis

All statistical measures were performed through the Statistical Package for Social Studies (SPSS) version 23 for windows. The current test involved two independent variables. The first one was the (tested group) between-subjects' factor which had two levels (Group A receiving electromagnetic field and Group B receiving aerobic exercise). The second one was the (training periods) within-subject factor which had two levels (pre and post). In addition, this test involved four tested dependent variables (weight, BMI, CRP, and LH/FSH). Preliminary assumption checking revealed that data was normally distributed for all dependent variables, as assessed by the Shapiro-Wilk test ($p > 0.05$); there were no univariate or multivariate outliers, as assessed by the boxplot and the Mahalanobis distance ($p > 0.05$), respectively; there were linear relationships, as assessed by the scatterplot; no multicollinearity. There was a homogeneity of variances ($p > 0.05$) and covariances ($p > 0.05$), as assessed by the Levene's test of homogeneity of variances and Box's M test, respectively. Accordingly, 2×2 mixed design MANOVA was used to compare the tested variables of interest at different tested groups and training periods. The MANOVAs were conducted with the initial alpha level set at 0.05.

Results

Baseline and demographic data

As indicated by the independent t-test, there were no statistically significant differences ($P>0.05$) between subjects in both groups concerning age and height (Table 1).

Table 1. Demographic characteristics of both groups:

	Group A	Group B	Comparison	
	Mean ± SD	Mean ± SD	t-value	P-value
Age (years)	26.4±3.97	26.46±2.74	-0.053	0.958
Height (m)	1.62±0.06	1.62±0.05	0.292	0.773

Statistical analysis using mixed design MANOVA analyzed thirty patients assigned into two equal groups. It revealed that there were significant within-subject (F= 180.584, p = 0.0001), treatment*time (F = 13.133, p = 0.0001) and between-subject effects (F = 3.199, p = 0.03*). Table 2 presents descriptive statistic and multiple pairwise comparison tests (Post- hoc tests) for the weight, BMI, CRP, and LH/FSH ratio. In the same context, the multiple pairwise comparison tests revealed that there was a significant reduction (p <0.05) in weight, BMI, CRP and LH/FSH ratio in the post-treatment condition compared with the pretreatment one in both groups. Regarding between-subject effects multiple pairwise comparisons revealed that there was a significant reduction (p < 0.05) in CRP and LH/FSH ratio in Group A compared with Group B, with no significant differences in weight and BMI between both groups (p > 0.05).

Table 2. Descriptive statistic and multiple pairwise comparison tests (Post hoc tests) for the weight, BMI, CRP, and LH/FSH ratio for both groups at different measuring periods.

	Group A		Group B	
Variables	Pre	Post	Pre	Post
Weight	91.33(8.10)	79.06(8.52	91.13 (8.52)	80.86 (7.16)
BMI	34.36 (1.24)	29.72 (1.5)	34.64 (3.21)	30.73 (2.67)
CRP	7.04 (1.65)	2.76 (1.27)	7.04 (1.84)	5.57 (1.51)
LH/FSH	2.19 (0.26)	1.51 (.2)	2.25 (.34)	1.83 (0.42)
Within groups (Pre Vs. post)				
p-value	Weight	BMI	CRP	LH/FSH
Group A	0.0001*	0.0001*	0.0001*	0.0001*
Group B	0.0001*	0.0001*	0.0001*	0.0001*
Between groups (group A Vs. group B)				
p-value	Weight	BMI	CRP	LH/FSH
Pre treatment	0.948	0.76	0.992	0.591
Post treatment	0.536	0.21	0.0001*	0.013*

*The mean difference is significant at the alpha level (p< 0.05).

Discussion

The results of this study showed that there was significant reduction (p <0.05) in weight, BMI, CRP and LH/FSH ratio in the post-treatment condition compared with the pretreatment one in both groups A and B. Regarding between-subject effects there was significant reduction (p < 0.05) in CRP and LH/FSH ratio in **Group A** patients who were receiving treatment with PEMF compared with **Group B** patients who were receiving treatment with aerobic exercise (both groups received the same diet program) with no significant differences in weight and BMI between both groups (p > 0.05).

Regarding the effect of PEMF, the results of the present study showed, a significant decrease in BMI and weight and this decreases were in agreement with another study which reported that there was a significant decrease in triglyceride and BMI, also there was a significant increase in low-density lipoprotein, and decline in high-density lipoprotein after application of Pulsed Magnetic Field with frequency 15 Hz, intensity 60 gauss and duration 20 min for 2 successive months. PEMF has a positive effect on BMI and Triglycerides (TGs) but it had a negative effect on Total Cholesterol (TC), LDL and HDL. The mechanisms for the effects of MF on lipid metabolism are not well understood yet but could be associated with lipid metabolism [15].

Interest in magnetic field therapy has been increased in the past years, it has been reported that it could be used as an alternative or complementary modality to alleviate inflammation. The results of the present study showed a significant decline in CRP which come in agreement with another study conducted on diabetic polyneuropathy to examine the effect of the magnetic field on CRP [16]. Also, CRP decreased by 60.79 % in another study applying 30 minutes of Pulsed electromagnetic field divided as follows; the device was adjusted for 5 minutes with frequency 2 Hz and 90% intensity, then 15 minutes with frequency 4 Hz and 100% intensity and finally 10 minutes' random frequency and 80% intensity. it was found that improvement in all measured parameter of weight, LH/FSH ratio, CRP, modified Ferryman–Gallwey scoring system and global acne grading system were decreased [17].

Every cell membrane carries an electromagnetic charge, and PEMFs alter this charge by causing movement of ions across the cell membrane, Studies have demonstrated that EMF can stabilize the cell membrane by restoring membrane protein activity ($Ca2+$ -ATPase) and maintain intracellular $Ca2+$ levels [18]. It appears to decrease the production of inflammatory cytokines IL-1β and tumor necrosis factor -α (TNF-α). EMF also appears to increase anti-inflammatory cytokine Interleukin-10 [19].

The results of the present study showed a significant decrease in LH/FSH ratio after receiving pulsed electromagnetic field in addition to diet control therapy, which agrees with the results of another study on adult female Sprague-Dawley rats that studied the effects of extremely low-frequency magnetic fields 50 Hz sinusoidal magnetic field at approximately 25 microT (rms) and found that there was a significant decrease in the levels of gonadotropins (FSH and LH) after six weeks of exposure (P < 0.005) as FSH levels were affected only on week 6 of exposure while LH remained affected during 12 and 18 weeks (P < 0.05**)** [20].

Regarding physical activity, the results of the present study showed the effect of aerobic exercise and combined diet in decreasing the BMI and weight. The alterations in body composition most often attributed to aerobic exercise are a decrease in fat weight and maintenance or slight increase in fat-free mass indicating the importance of aerobic exercise in burning calories and losing body fat [21].

Reduction in CRP in the current study come in agreement with the study reported that diet plus exercise (walking on treadmill 3 days/week) were effective in reducing inflammatory markers, (CRP, interleukin-6 and TNFα) [22].

It was also reported that four months of aerobic exercise of intensity 60–80% of maximal oxygen consumption (VO2 max) in addition to diet was effective for decreasing CRP [23].

Also, it was found that diet plus exercise training program included three training sessions per week on cycle ergometers was associated with a reduction in CRP [24].

From the previous literature who studied the effect of aerobic exercise on CRP, the present study suggested a possible explanation for its mechanisms of action as follows: Exercise training-induced improvements in inflammatory status may result from the modulation of intracellular signaling pathways and cellular function that are mediated by nitric oxide (NO) and reactive oxygen species (ROS). While ROS and NO are generated at low rates under resting conditions, the production of these molecules increases transiently during exercise and plays a role in inducing anti-inflammatory defense mechanisms [25].

Regarding the decrease on LH/ FSH ratio, in a study which conducted 8 weeks of combined diet and aerobic exercise, the results showed agreement with the results of the current study as there was weight loss ($p<0.05$), body fat decreased ($p<0.05$), and increased insulin sensitivity (32% increase, $p<0.05$) and improvement in estradiol and LH:FSH ratio [26]. It was also found that moderate-vigorous exercise may increase the sensitivity and responsiveness of the follicles to FSH and LH with an increase in the ovulatory status [27].

Physical exercise specifically causes suppression of hypothalamic pulsatile release of GnRH, which normally occurs every 60–90 min, limits pituitary secretion of luteinizing hormone (LH) and, to a lesser extent, follicle-stimulating hormone (FSH), which, in turn, limits ovarian stimulation and estradiol production [28]. Exercise-induced weight loss has been shown to improve metabolic function and hormonal profiles and often leads to a significant increase in fertility [29]. Although the current study presents objective data with statistically significant differences, there are some limitations in this study. First limitation is the small number of cases recruited and the second is the lack of follow-up.

Conclusion

Both PEMF and aerobic exercise were effective in decreasing the inflammatory level (decreasing CRP) and improving the ovulation through decreasing LH/FSH ratio but pulsed electromagnetic field was more effective than aerobic exercise in reducing CRP and LH/FSH ratio in PCOS women with no difference in its effect on the body weight or the BMI.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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