Electromagnetic field versus diclofenac drugs on primary dysmenorrhea.

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Abstract

Background: Primary dysmenorrhea is one of the most common complaints of women and is also the most common gynecological problem worldwide**.** These cramps are recurrent and 90% adolescent girls and about 50% women suffer from it**.Purpose ofthe study**: to determine which is more effective in treatment of primary dysmenorrhea;pulsed electromagnetic field ordiclofenac drugs.**Methodology:** Fifty adult femalesparticipated in this study, their age ranged from 17 to 24 years and their body mass index was ranged from 20 to 25 kg/m^2.They were divided randomly into two groups equal in numbers:group (A)received pulsed electromagnetic field applied on pelvic region,3 times per week for 3 months, 20 minutes per day and group(B) received diclofenactablets, 50 mgonly with onset of menstrual pain. All participants in both groups (A and B) were assessed pre- and post-treatment through measuring progesterone level in the blood, assessment of pain using visual analogue scale and physical as well as psychological symptoms by using menstrual symptom questionnaire.**Results:**revealed that pre-treatment, there was a non-statistical significant difference between both groups (A&B) in median value of pain, menstrual symptoms questionnaire&progesterone where the p-value was (>0.05). comparison between pre and post treatment showed a statistically highly significant improvement in pain, physical andpsychological symptoms associated with dysmenorrhea and progesterone blood level in group (A) than in group (B). **Conclusion:**pulsed electromagnetic field was effectivethan diclofenac drugsin relieving pain and associated symptoms with dysmenorrhea.

Key Words: Primary Dysmenorrhea- Pulsed electromagnetic field-Diclofenac drugs.

INTRODUCTION

Dysmenorrhea is the most common gynecological complaint among adolescent and young adult females**(1)** with a major impact on women's quality of life, work productivity, and health- care utilization **(2&3).**It is defined as painful menses in woman with normal pelvic anatomy, usually beginning during adolescence, may be categorized into two distinct types: primary and secondary dysmenorrhea **(4).**Primary dysmenorrhea is associated with normal ovulatory cycles with no pelvic pathology. In primary dysmenorrhea pain begins few hours before or after the onset of menstruation and lasts for 24 – 48 hours. The pain is more in the first day and rarely continues to next day. Dysmenorrhea pains are felt in lower abdomen and radiate into inner parts of thighs. In a high percentage of cases, girls may experience systematic symptoms such as backache, nausea, vomiting, diarrhea, fatigue and headache **(5).** The pain appears to be the effects of prostaglandins released by the disintegrating endometrium during menstruations **(6).**Clinical research has identified a physiological reason for dysmenorrhea as increase production of uterine prostaglandins. During endometrium sloughing endometrial cells release prostaglandins as menstruation begins. Prostaglandins stimulate myometrium contractions and ischemia.Prostaglandins arealso implicated insecondary dysmenorrhea **(7).** Several approacheshave been proposed for dysmenorrhea, including non-steroid anti-inflammatory drugs (NSAID), oral contraceptives and vitamins **(8).**Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) that is the most common treatment for both primary and secondary dysmenorrhea. Non-pharmacologic approach interventions such as herbal preparations**(9)**, transcutaneous nerve stimulation, **(10)**, acupuncture **(11)** and heat therapy **(12)**have been reported to lessen dysmenorrhea in some studies. Pulsed Electromagnetic fields (PEMF) are now used as one of the efficient modalities in field of physical therapy for treatment of many pathological conditions, it exhibits the following activities for decreasing pain, including: selective attenuation of neuronal depolarization by altering membrane resting potential, increasing blood flow potentially accelerating tissue healing and removing noxious mediators, altering ion binding kinetics and therefore modulating release of cytokines and other inflammatory mediators **(13).**NSAID andPEMFeffective in relieving pain of primary dysmenorrhea by decreasing prostaglandin level in the blood leads to less vigorous contractions of the uterus and to less discomfort**(14&15).**

SUBJECTS AND METHODS

Subjects

Fifty adult femalesparticipated in this study, their age ranged from 17-24 yearsand their body mass index was ranged from 20 to 25 kg/m^2.They were divided randomly into two groups equal in numbers: group (A)received pulsed electromagnetic field applied on pelvic region,3 times per week for 3 months, 20 minutes per day and group (B) received only diclofenac tablets, 50 mg only withthe onset of menstrual pain for 3 months. All participants in both groups (A and B) were assessed pre- and post-treatment through measuring progesterone blood level, assessment of pain by using visual analogue scale and physical as well as psychological symptoms by using menstrual symptom questionnaire.

Study excluded girls with Irregulars or infrequent menstrual cycles, Pacemaker, Myasthenia gravis, hyperthyroidism, active tuberculosis and psychosis. All girlsin both groups (A and B) were given a full explanation of the treatment protocol and a written informed consent form giving agreement to participation.

Methods

All medical, obstetric and menstrual history was taken from each female in both groups (A and B) to confirm there were no any contraindications that interfere the study. Pain assessedbefore and after treatment procedure (3 month); in both groups (A and B) byvisual analogue scale**(16)**, it is a graphic rating scale with numerical values placed equidistantly along the line. The descriptors and numbers help the subject to place her estimate on line in which (0) mean no pain, (1) equal mild pain, (2) equal moderate pain, (3) mean severe pain and (4) mean unbearable pain, this test was applied to determine the severity of pain, Sample of blood was taken to detect the level of progesterone and menstrual symptom questionnaire**(17)**to assess symptoms of dysmenorrhea. Pulsed electromagnetic field device used was EASY Qs portable (by ASA, Italy) magnetic therapy device which generate frequency from 5-100 Hz and intensity from 1 to 60 Gauss. Group (A) received 20min 3 times per week for three month with strength 60 gauss and frequency 50 Hz, from comfortable modified supine lying position with small pillows under her body curves. Then, PEMF applied one electrodes above suprapubic region and another electrode on the lumbar region from (T10 – L1) supported by long strap. While, group (B) received only diclofenactablets (50 mg)few hours at the onset of menstruation for 3 months.

STATISTICAL ANALYSIS

The data of this study were analyzed statistically by using the following: Results are expressed as mean ± standard deviation, median, minimum and maximum. Test of normality, Kolmogorov-Smirnov test, was used to measure the distribution of data measured pre-treatment. Accordingly, comparison between normally distributed data in the two groups was performed using unpaired t test. Comparison between not normally distributed variables in the two groups was performed using Mann Whitney test. Comparison between variables measured pre- and post-treatment in the same group was performed using Wilcoxon Sign Rank test.Statistical Package for Social Sciences (SPSS) computer program (version 19 windows) was used for data analysis. P value ≤ 0.05 was considered significant.

RESULTS

1-Physical characteristics of the patients

There were no statistical significant differences between both groups (A and B) in their ages, weight, height and body mass index, where their T and P values were (0.526, 0.601), (-0.860, 0.394), (-1.665, 0.102) and (0.482, 0.632) respectively(Table.1).

Table.1: Physical (general) characteristics of the two studied groups.

Variables	Group (A) (n= 25)	Group (B) (n= 25)	T value	P value
Age (yrs.)	21.72 ± 2.03	22.04 ± 2.26	0.526	0.601 (NS)
Weight (Kg.)	60.64 ± 5.85	59.36 ± 4.60	-0.860	0.394 (NS)
Height (cm.)	160.60 ± 5.27	158.28 ± 4.56	-1.665	0.102 (NS)
BMI (kg/m^2)	23.48 ± 1.57	23.68 ± 1.40	0.482	0.632 (NS)

2-Pain intensity

Before treatment, there was no statistical significant difference between the median value of pain in group (B)[4.0 (2.0-4.0)]score and its corresponding value in group (A)[3.0 (2.0-4.0)] score with Z value = -0.996 and p value = 0.319 (Table.2).

After treatment, there was a statistical significant decrease in the median value of pain in group (A)[1.0 (0.0-2.0)] score when compared with its corresponding value in group (B)[2.0 (1.0-3.0)] score with Z value = -5.234 and p value = 0.001 (Table.2).

Table.2: Intergroup comparison between median values of pain in the two studied groups measured pre- and post-treatment.

Data of assessment	Group (A) (n= 25)	Group (B)(n= 25)	Z value	P value
Before treatment	3.0 (2.0-4.0)	4.0 (2.0-4.0)	-0.996	0.319 (NS)
After treatment	1.0 (0.0-2.0)	2.0 (1.0-3.0)	-5.234	0.001*

3-Menstrual symptoms questionnaire

Before treatment, there was no statistical significant difference between the median value of menstrual symptoms questionnairein group (B)[30.0 (21.0-35.0)] score and its corresponding value in group (A)[29.0 (20.0-36.0)]score with Z value = -0.798 and p value = 0.425 (Table.3).

After treatment, there was a statistical significant decrease in the median value of menstrual symptoms questionnairein group (A)[17.0 (12.0-28.0)] score when compared with its corresponding value in group (B)[22.0 (12.0-31.0)]score with Z value = -3.504 and p value = 0.001 (Table.3).

Table.3: Inter comparison between median value of menstrual symptoms questionnaire in the two studied groups measured pre- and post-treatment.

Data of assessment	Group (A) (n= 25)	Group (B) (n= 25)	Z value	P value
Before treatment	29.0 (20.0-36.0)	30.0 (21.0-35.0)	-0.798	0.425 (NS)
After treatment	17.0 (12.0-28.0)	22.0 (12.0-31.0)	-3.504	0.001*

4- Progesterone blood level

Before treatment, there was no statistical significant difference between the median value of progesterone in group (B) [5.6.0 (1.0-16.02)]ng/ml and its corresponding value in group (A) [3.16 (4-12)]ng/ml with Z value = -1. 087 and p value = 0.227 (Table.4).

After treatment, there was a statistical significant increase in the median value of progesterone in group (A)[8.85(4.08-17.81)]ng/mlwhen compared with its corresponding value in group (B)[5.41 (.2-15.76)]ng/ml with Z value = -2.659 and p value = 0.008 (Table.4).

Table.4: Inter -group comparison between median value of progesterone in the two studied groups measured pre- and post-treatment.

Data of assessment	Group (A) (n= 25)	Group (B) (n= 25)	Z value	P value
Pre-treatment	3.16 (0.4-12.0)	5.6 (0.10-16.02)	-1.087	0.277 (NS)
Post-treatment	8.85 (4.08-17.81)	5.41 (0.20-15.76)	-2.659	0.008*

DISCUSSION

Dysmenorrhea is a common problem in women of reproductive age. Primary dysmenorrhea is defined as recurrent, cramping pain occurring with menses in the absence of identifiable pelvic pathology**(18).**Evidence suggests that most women with primary dysmenorrhea have increased or abnormal uterine prostanoid production and release, giving rise to abnormal uterine activity and therefore to pain(**19).**

Associated general symptoms, such as nausea, vomiting, lumbago, diarrhea and headache are the sequel of influx of prostaglandin and its derivatives into systemic circulation **(20).** It was reported that progesterone inhibits prostaglandin synthesis and therefore decreases myometrial contractility by blocking prostaglandin action, decreasing prostaglandin synthesis and increasing its rate of inactivation**(21).** Today, magneto-therapy provides a non-invasive, safe, and easy method to directly treat the site of injury, the source of pain and inflammation, and a variety of diseases and pathologies**(22).**Magnetic stimulation offers a new treatment option for patients with chronic pelvic pain who do not respond to pharmacotherapy **(23).**The NSAIDs specifically approved by the US Food and Drug Administration (FDA) for treatment of dysmenorrhea**(24).**In this study fifty adult females were suffering from primary dysmenorrhea; they were divided randomly into two groups equal in numbers: group (A)received pulsed electromagnetic field applied on pelvic region,3 times per week for 3 months, 20 minutes per day and control group (B) received onlydiclofenac tablets (50 mg) few hours before or after the onset of menstruation for 3 month.Results indicated that pre-treatment, there was a non-statistical significant difference (P> 0.05) between both groups (A&B) in median value of pain, menstrual symptoms questionnaire& progesterone. While, post-treatment, there was a highly statistical significant difference (P<0.001) between both groups (A&B) in median value of pain, menstrual symptoms questionnaire and progesterone favorin group (A) than in group (B). So,pulsed electromagnetic field was effective than diclofenac drugs in relieving pain and associated symptoms with dysmenorrhea

The result of this study agreed with those of Abdel-Fatah and Shaheen **(25)** who studied the effect of pulsed electromagnetic field (PEMF) in treatment of primary dysmenorrhea. They studied onthirty volunteers girl suffer from primary dysmenorrhea, There was highly statistically significant decrease in menstrual pain intensity, highly statistically significant decrease in prostaglandin level in blood and improvement in physical and psychological symptoms that associated with dysmenorrhea, after treatment program. Therefore, PEMF is effective in relieving pain of dysmenorrhea.

Also the result of current study in line with those of Scisciolo et al. (**26**) who studied effects of repetitive magnetic stimulation in the treatment of chronic pelvic pain syndrome and floor dysfunction. They studied on 48 patients with chronic pelvic pain. After five weeks of PEMF exposure (2 day per week), Pain remission was reported in 67% of patients who stimulated with repetitive magnetic stimulation both the site of pain and the sacral spinal cord than placebo controlled patients.

The results of this study agreed with Moffett et al. **(27)** who stated that PEMF treatment is followed by changes in the gene expression profiles of a number of factors associated with inflammation and analgesia including: stimulate the expression of cytokines and metabolic pathways involved in dampening and resolving the inflammatory response and increase in endogenously expressed opioid precursors, both at the messenger (m) RNA and peptide levels.

The results of current study agree with those of Jahromy et al. **(28)** who examined the effects of extremely low frequency magnetic field (ELF-MF) on formalin induced chronic pain on mice. In this experimental study, thirty two adult male mice were used and divided into 4 groups (n = 8). Three groups of animals exposed daily for thirty minutes to 25, 50, 75 HZ (intense 250 μT) of electromagnet field for one week, respectively and one group considered as control with no exposure. At the end of a week, formalin test was performed. They reported that, PEMF is effective to reduce

formalin induced chronic pain in mice at both acute and chronic phases and the most effective responses were obtained at 50 HZ frequency.

Concerning the effect of PEMF on progesterone level in the blood, the result of current study in line with thoseof Katalin, P. et al. **(29)**whoreported thatthere was significant increase in progesterone production by granulosa cells obtained in patients who exposed to magnetic field. Concordantly, in the present study, the PEMF has positive effect on progesterone.

On the other hand, the results of this study disagree with those of Beaulieu et al. **(30)** who reported that PEMF does not directly influence pain perception in healthy individuals.

Also the result of current study on progesterone disagreed with those of Huuskonen et al. **(31)** whorevealedthat 50-Hz sinusoidal magnetic fields did not influence the serum progesterone level**.**Therefore,results of current study support the fact that pulsed electromagnetic is an effective adjuvant treatment for relieving pain and associated symptoms of dysmenorrhea than diclofenac drugs but there is no doubt that more studies need to be carried out in order to clarify the effect of PEMF on progesterone and ovulation.

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