EFFECT OF PULSED ELECTROMAGNETIC FIELD THERAPY ON PAIN AND LEUKOCYTE COUNT IN PATIENTS WITH ILEUS FOLLOWING ABDOMINAL SURGEREIES

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ABSTRACT

Background: *Postoperative ileus (POI), a frequent and serious issue following abdominal surgeries, is characterized by paralysis of the intestine. This condition can lead to several complications, such as delaying the administration of enteral nourishment, causing discomfort to the patient, and lengthening the hospital stay.* ***Objective:*** *To determine the impact of pulsed electromagnetic field therapy (PEMFT) on pain as well as leukocyte count in patients with ileus following abdominal surgeries. Methods: This study included 30 patients, 10 women and 20 men, ranging in age from 25 to 55 years, who had recently undergone abdominal surgery. They were randomized into 2 groups of same number; study group (A) was given the PEMFT, while control group (B) was given the placebo PEMFT. In addition to PEMFT, patients in the 2 groups also received the same medical care and medications at 1st day and continued for 6 days postoperatively. Measurement of this study includes visual analogue scale (VAS) and Leukocytes total count (LTC) that were assessed before and after the treatment program and the treatment program was applied daily for 6 days.* ***Results:*** *The two groups demonstrated significant improvements in all measured variables, additionally, all evaluated variables' post-test mean values demonstrated statistically significant differences favoring groups (A) ($P < 0.05$).* ***Conclusion:*** *PEMFT had a positive effect on pain and leukocyte count in patients with ileus following abdominal surgeries.*

Keywords: *Pain; Leukocytes; Post abdominal surgeries; Post-operative ileus; Pulsed electromagnetic field.*

INTRODUCTION

Impaired gastrointestinal transit, often Impaired gastrointestinal transit, often known as post-operative ileus, can develop after abdominal surgery (1). Furthermore, it is a surgical complication resulting from a dysfunction in the movement of the gastrointestinal tract, with an occurrence rate ranging from 10 to 30% (2). POI is the primary reason for an extended hospital stay after abdominal surgery (3).

POI is a frequent complication that occurs after colorectal surgery. It is characterized by the inability to restore normal peristaltic motions in the gastrointestinal tract, even when there is no mechanical obstruction (4). POI presents with symptoms such as abdominal distension, nausea, vomiting, in addition delayed oral intake. In certain cases, a decompression tube may be necessary to alleviate these symptoms (5).

The consequences of pathological POI include a delay in food intake, an extended need for parenteral nutrition, pain, and an extended hospital stay. Occasionally, vomiting linked with POI can lead to life-threatening conditions due to the risk of aspiration. POI can potentially extend patients' employment disability and escalate treatment expenses (6).

Additionally, an extended period of POI can lead to a range of problems including malnutrition, muscular wasting, delayed healing of surgical wounds, and pneumonia. These complications might result in an extended hospital stay and increased costs for hospitalization (7).

Individuals who have undergone abdominal surgeries, including procedures involving the colon and rectum, are susceptible to developing POI (8). The efficacy of preventive measures for preventing POI, such as thoracic epidural anesthetic, gum chewing, as well as avoidance of water excess, has been limited (9).

A noninvasive method, PEMFT uses electromagnetic fields to induce microcurrents across the body or to target particular tissues locally (10-12). The site of the lesion, which is the origin of pain as well as inflammation in many diseases and pathologies, can be immediately treated using PEMFT in a safe and easy way (13).

For the relief of pain, edema, and swelling, it has received FDA approval for use in

(14). Some of the ways in which PEMFT helps the body's tissues are by reducing inflammation and pain, increasing the rate at which edema is reduced, increasing the absorption of hematoma, stimulating osteogensis, acting as an anti-infective, and speeding up the healing of the peripheral and central nervous systems (15).

Scientific evidence has conclusively shown that tissues such as blood, muscle, ligaments, bone, as well as cartilage react to biophysical stimuli, including electrical in addition electromagnetic fields (16). In the field of physical therapy, it has been utilized as an effective therapeutic technique for several disorders. It demonstrates vasodilation, analgesic properties, anti-inflammatory effects, and anti-edematous activity (17).

Numerous diseases and conditions can be alleviated with the use of PEMF in the 0-300 Hz range. These include osteoarthritis, Parkinson's disease, postoperative pain and swelling, chronic wounds, and the promotion of vasodilatation and angiogenesis, which in turn stimulate excitable cells like nerve and muscle cells (10-12).

There is a lack of knowledge and limited studies that focused on the impact of the PEMFT on pain and leukocytes total count among patients with ileus following abdominal surgeries. Therefore, the purpose of this research was to examine the impact of PEMFT on pain and

leukocyte count in patients with ileus following abdominal surgeries.

MATERIALS AND METHODS

2.1. Study design

This study was a randomized controlled trial. Detailed explanations of the study's methods and objectives were provided to the patients who agreed to participate in the research. Researchers checked their eligibility for the study and collected basic demographic information through a short interview. Be assured, all patient information will remain private.

The research was authorized by the Research Ethical Committee of Cairo University's Faculty of Physical Therapy in Giza, Egypt, and it took place from May 2021 to August 2022 (P.T.REC/012/003138). A comprehensive consent form outlining the study's procedures and aims was provided to patients and legal guardians of potential participants.

2.2. Randomization

The randomization was conducted using a computer-generated block randomization tool available at http://www.randomization.com/. The participants were assigned randomly into groups of either 6 or 9, with an equal number of individuals in each group. The process of concealed allocation was carried out by utilizing sealed, sequentially numbered opaque envelopes. The randomization was conducted by an unbiased researcher who had no involvement in the recruitment process, data collection, or therapy.

2.3. Sample size calculation

The sample size was determined using the G*Power software (version 3.0.10). The F-test for MANOVA was chosen to analyze the interaction effects within and between groups. To achieve a power of 0.80, an alpha level of 0.05 (two-tailed), and an effect size of 0.4, a minimum sample size of 30 people, with 15 participants per group, was necessary.

2.4. Participants

Thirty patients of both genders (10 women and 20 men) with ileus following abdominal surgeries were recruited from the outpatient clinic of the the surgery departments of Kasr-El-Aini and Om-Al-Misrieen Hospital, Giza, Egypt.

The inclusion criteria of the patients were: they were referred by surgeon for the treatment, their aged ranged from 25-55 years, they underwent abdominal surgeries (cholecystectomy, colectomy and splenectomy), they suffering from persistent or unresolving POI, they were non smokers, not alcohol drinkers and had no systemic disease, they were not familiar with the technique of the PEMFT application and their POI was the non-mechanical obstruction. We excluded patients with immunodeficiency disorders, mechanical POI, cardiac pacemakers, skin abnormalities (skin malignancy in the treated area), diabetic patients or familiar with the techniques of the PEMFT application and pregnant women.

The chosen patients were randomized to two groups of equal size. The two groups were given the same medical care and medications after 6 days postoperatively. Group (A) was given the true PEMFT, while group (B) was given the placebo PEMFT.

As presented in the flow chart in (Figure 1), A total of 43 patients met the criteria for inclusion in this study, but 13 patients were excluded because they lived too far away. The remaining 30 patients were randomly assigned using the Block Stratified Randomized Software program (version 6.0 of the randomization program, Rand.exe) with block sizes of 4, 2, and 6. However, due to the presence of multiple stratified variables, it was challenging to

evenly distribute the samples into two groups with equal numbers [18]).

2.5. Outcome measures

2.5.1. Visual analogue scale (VAS):

It is considered as reliable and valid method available for estimation of pain intensity pain level. It is a horizontal line that is perfectly straight and has a predetermined length, typically measuring 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health) orientated from the left (worst) to the right (best). Some studies employ a horizontal orientation for scales, with a right-to-left direction, but many researchers utilize vertical VAS. Patients are requested to specify the position on a scale ranging from 0 to 100 mm, where 0 cm signifies the absence of pain and 10 cm symbolizes the furthest intense pain that can be imagined.

The majority of studies demonstrated that the VAS is a viable and accurate measurement tool. Furthermore, it can be classified as an interval scale. In clinical practice, this scale can be utilized as a tool for measuring pain and assessing outcomes (19, 20).

2.5.2. Leukocytes total count (LTC) (PeproTech Inc., Rocky Hill, USA):

Peripheral blood was drawn from each patient and on the first and six postoperative days in the morning, together with the routine blood tests. Leucocytes measurement was a part of the standardized care (21).

2.6. Therapeutic procedures

Before starting the evaluation, all procedures were explained to the participating patients. Each patient who took part in the trial had an evaluation sheet filled out, which included the factors measured both before and after the 6-day treatment.

2.6.1. Intervention:

2.6.1.1. Pulsed electromagnetic field therapy (PEMFT):

The PEMF device used in this study (RecoveryRx, BioElectronics Corp, USA) is a battery-powered 12-cm elliptical coil radiofrequency energy generator (frequency = 27.1 MHz, pulse rate = 1000 per second, pulse duration = 100 ms). Wipes containing 70% isopropyl alcohol were used to clean and sanitize the device's surface before it was applied. The first wipe eliminated any visible dirt or grime.

After that, the device's surface area was disinfected with a second wipe. In order to disinfect the device, the wipe had to come into touch with its whole surface for a minimum of three seconds. It was done in accordance with what surgeons typically do (22).

Preparation:

Each patient must not wear any metal objects during the magnetic field application or anything sensitive to magnetic field, such as chains, belts, watches. Mobile phones were apart from the equipment. The treatment was applied while the female lying in a comfortable modified side lying position with small paddings under her body curves. Information about the magnetic apparatus and the protocol of treatment were introduced and explained to the patients before treatment (23).

Position and intervention of patient:

Patients were randomly allocated to one of two treatment groups, either placebo or PEMF wearable device. Patients in the treatment group were given a PEMF wearable device (PEMF group). Patients in the placebo group were given a device with no electromagnetic properties (placebo group) (24).

The device used in the present study that emits a safe form of non-ionizing electromagnetic radiation. The carrier frequency is 27.12 MHz, the assigned Federal Communications Commission medical frequency, and it has a pulse rate of 1000 Hz and a 100 μs burst width. The peak burst output power of the 12 cm antenna is ∼0.0098 W and covers a surface area of ∼103 cm2. The circuitry consists of low-voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic radiofrequency field, with the antenna field placed directly above the therapeutic site. This closed-loop system of the antenna, low-energy signal generator circuit and battery power supply transfers the radiofrequency energy to the tissue. The placebo devices do not emit a radiofrequency electromagnetic field but are identical to the active devices, including a light-emitting diode light showing operation. The energy from the active device is not felt by the user, and the active device cannot be distinguished in any way from the placebo device (24).

The therapeutic procedure lasted for a total of 20 minutes. The patient positioned in a comfortable left lateral posture, with their trunk at a 45º angle to the couch. The paravertebral PEMFT or placebo application at the thoracolumbar junction (origin of the sympathetic outflow) for 10 minutes (5 minutes for each side paravertebrally) Next, the patient was positioned in a supine posture with the hips slightly flexed and rotated to the side, the knees slightly flexed (only 10 degrees), and the ankles slightly plantar flexed. A pillow was placed under the patient's head to ensure a comfortable position. The active surface of the PEMFT device was applied with contact technique for another 10 minutes application on the right iliac fossae (5 minutes) and left (5 minutes) along the ascending and descending colon (on the two sides of the hypogastric region that lie in the middle and below the umbilical region) (25, 26).

The PEMFT application was initiated in the hospital room from the first postoperative day. It was advised to maintain continuous stimulation for 6 days postoperatively (27, 28).

Statistical analysis:

The chi-square test was employed to identify the distribution of sexes. In presenting all of the study's data, standard deviations as well as means were utilized. The unpaired t-test was utilized to compare the characteristics of subjects across groups. To assess the normality of the data distribution, the Shapiro-Wilk test was employed. The Levene's test was used to assess the homogeneity of variances among the groups. In order to compare the study's variables between groups, researchers utilized paired t-tests to look for significance within each group while unpaired t-tests to find significance between two groups. All statistical analysis was carried out using SPSS version 23 for Windows, which is a program developed by IBM SPSS in Chicago, IL, USA.

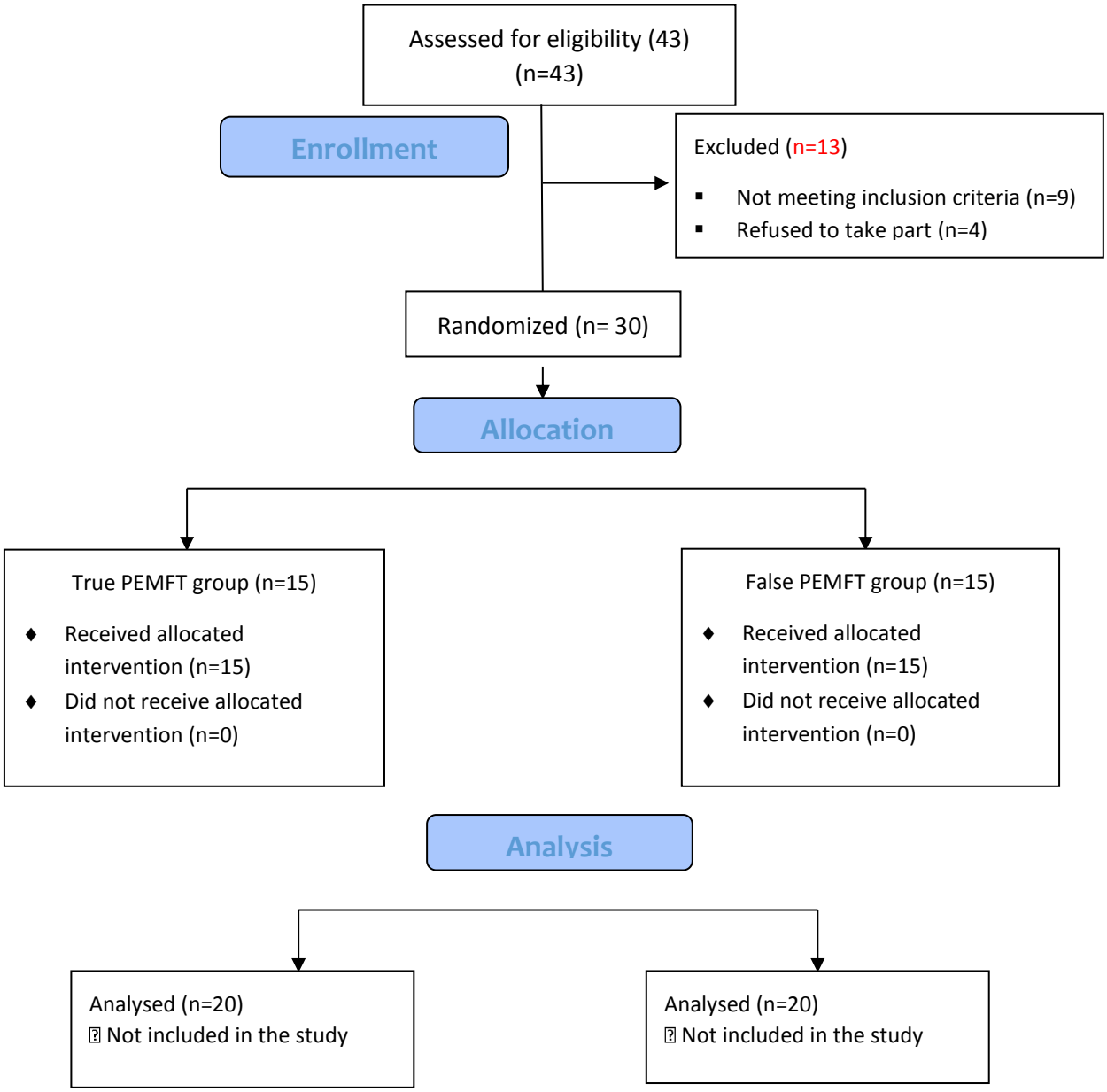

Figure (1): The flow chart of the study.

Results

A) Patients demographic data:

The mean values concerning age for groups (A & B), there was no substantial difference among the three groups ($p > 0.05$) (Table 1).

Table (1): Comparison of age between the three groups (A and B).

	Group (A) $\overline{X}$ ± SD	Group (B) $\overline{X}$ ± SD	t-value	p-value	Level of significant
Age (years)	42.53 ± 9.09	42.4 ± 9.12	1.47	0.164	N.S

$\overline{X}$: Mean. SD: Standard Deviation. t-value: Unpaired t test value.

p-value: Probability value. NS: Non-Significant.

The gender distribution of group (A) revealed that there were 6 (40%) women as well as 9 (60%) men while group (B) revealed that there were 4 (26.67%) women as well as 11 (73.33%) men. There was no substantial difference among the two groups ($p > 0.05$) as in (Table 2).

Table (2): Comparison of gender distribution between both groups (A and B).

	Gender distribution N (%)		X^2	p-value	Level of significant
	Group (A)	Group (B)			
Women	6 (40%)	4 (26.67%)	1.35	0.535	NS
Men	9 (60%)	11 (73.33%)			

$\overline{X}$: Mean. SD: Standard Deviation. X^2: Chi squared value.

p-value: Probability value. NS: Non-Significant.

B) Measured variables:

1) Pre- treatment comparison between the two groups (A and B):

Comparison the pre- treatment $\overline{X}$ ± SD values of VAS as well as TLC among groups (A and B), non substantial differences of all measured variables were revealed between the two groups ($p > 0.05$) (Table 3).

2) Pre and post- treatment comparison for groups (A and B):

Comparison the pre as well as post- treatment $\overline{X}$ ± SD values of VAS in addition TLC within groups (A and B), substantial differences of all measured variables were revealed within the two groups ($p < 0.05$) (Table 3).

3) Post- treatment comparison between the two groups (A and B):

Comparison among the post- treatment $\overline{X}$ ± SD values of VAS in addition TLC between groups (A and B), substantial differences of all measured variables were revealed among the three groups ($p < 0.05$) (Table 3).

Table (3): Comparison of VAS and TLC between groups (A and B).

		Group (A) $\overline{X}$ ± SD	Group (B) $\overline{X}$ ± SD	t-value	p-value
VAS	Pre-treatment	8.67±0.62	8.48±0.21	0.32	0.748^{NS}
	Post-treatment	4.53±0.52	6.54±0.41	12.65	0.001^{S}
	t-value	18.96	11.04		
	p-value	0.0001^{S}	0.005^{S}		
TLC	Pre-treatment	5440.27±73.68	5433.12±56.13	0.27	0.789^{NS}
	Post-treatment	4220.56±94.11	5101.66±61.78	42.54	0.017^{S}
	t-value	43.66	13.82		
	p-value	0.0001^{S}	0.03^{S}		

$\overline{X}$: Mean. SD: Standard Deviation. t-value: Paired and Unpaired t- test value. p-value: Probability value. NS: Non-Significant. S: Significant.

DISCUSSION

This study investigated the effect of PEMFT on pain as well as leukocytes total count in patients with ileus following abdominal surgeries. We observed substantial differences in all evaluated variables before and after the treatment in both groups. At the same time, there was a substantial difference in the post-treatment mean values in favor of PEMFT compared to placebo PEMFT group.

Nevertheless, there is a scarcity in the published literature regarding the effect of PEMFT on chronic wound healing and pain relief (29). Electromagnetic treatments rely on the time-varying electromagnetic field (EMF) that is consistently generated at low wavelengths via an alternative current passing through a coil (30). The greatest potential of PEMF was demonstrated in its ability to augment the impact of inflammation by decreasing inflammatory cytokines and enhancing cellular metabolism (31).

When compared between pre as well as post treatment results of group (A), the significant of VAS scores is presented that are confirmed with Choi et al., (32) who said that PEMF has been therapeutically utilized as an intervention to improve the healing process of chronic ulcers. Prior research has demonstrated that PEMF improved the healing process of wounds, alleviated wound discomfort, improved the formation of healthy granulation tissue, and stimulated blood flow.

On comparing the results of pre and post-treatment programs in our study, the significant decrease of TLC of group (A) aligned with those found by Vianale et al., (33) who found that PEMFT had positive effects on white blood cells (WBCs) count were used as markers for monitoring infection and microbial

eradication, that's because they both increase rapidly in concentration following infection.

Also, the findings of the study applied by Athanasiou et al., (34) is accepted with the results of our study in group (A) who found that PEMFT had significant effects on WBCs count after exposure that denotes inhibition of the phagocytosis and opsonization resulting from successful microbial eradication and resolved infection.

When compared between pre and post treatment results of VAS of group (B), the significant of VAS scores are confirmed with Nurhayati and Madsiri, (35) who said that Effective pain management after abdominal surgery requires a mix of pharmaceutical and non-pharmacological approaches.

On comparing the results of pre and post-treatment programs in our study of group (B), it was accepted with the results of Tano et al., (36) who confirmed the level of patient satisfaction with the post-operative pain management services provided by healthcare providers was generally high. However, the extent of satisfaction varied significantly based on factors such as the specific analgesics and pain relief methods utilized, the ability to request additional pain relief, and the availability of information regarding pain treatment.

The post treatment results of group (B) showed the significant decrease of TLC that are agreed with Bauer and Boeckxstaens, (37) who established that after POI that is caused by an enteric molecular inflammatory response, the amount of leucocytes decreased gradually into the muscularis of the intestinal segments manipulated during surgery.

When comparing post treatment results between groups (A and B), the significant differences of all measured variables come in favor of group (A) that are in agreement with the results of Elgohary and Tantawy, (38) who stated that PEMF is an all-encompassing technique utilized in the management of a wide range of medical dysfunctions, including but not limited to musculoskeletal disorders, neurological presentations, and urological fields. The precise mechanism by which PEMF exerts its beneficial effects on living organisms is not yet fully understood; nevertheless, clinical studies have documented its beneficial effects on pain relief, inflammation reduction, and the formation of new blood vessels.

Limitations:

A few limitations of this study should be noted, including a small sample size that may restrict the generalizability of the results and the fact that the effectiveness of interventions was evaluated only six days after their implementation. As a result, the findings of the study failed to provide any indication of the durability of the enhancements subsequent to the intervention.

Strength:

Our attempt to establish the impact of PEMFT on pain as well as TLC post abdominal operations, which has not been reported before, could be viewed as a strength of the current study because it uses an objective, valid, as well as trustworthy measurement instrument.

CONCLUSION

This study demonstrates that the positive outcomes observed provide a foundation for further research exploring the long-term benefits of treatment program and its potential to enhance overall functional abilities and quality of life in this population.

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Conflicts of interest:

No conflict of interest has been declared by the authors of this academic work.

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