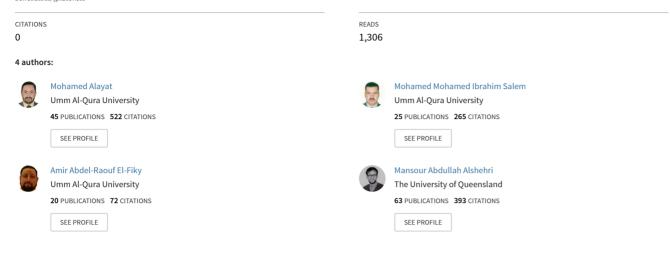
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Efficacy of pulsed electromagnetic field on pain and function in chronic mechanical neck pain: a randomized controlled trial

Article *in* International Journal of Physiotherapy and Research · April 2017 DOI: 10.16965/ijpr.2017.105



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EFFICACY OF PULSED ELECTROMAGNETIC FIELD ON PAIN AND FUNCTION IN CHRONIC MECHANICAL NECK PAIN: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Mechanical neck pain (MNP) is a common neck disorders affecting middle-aged population. Magnetotherapy is considered as a safe and non-invasive physical therapy modality used in the treatment of musculoskeletal pain.

Subjects and Methods: A total of 60 male patients participated in this study. Their mean age, weight, height, body mass index (BMI) and duration of illness were 23.03 (2.239) years, 63.43 (5.195) Kg, 1.662 (5.1092) cm, 22.98 (1.879) Kg/m², 4.483(1.228) months respectively. They were randomly assigned in to two groups. Group I (30 Patients) was treated with PEMF plus exercises (PEMF+EX) group and group II (30 Patients) treated with placebo magnetic plus exercises (PL+EX) group. Exercise program included active range of motion, muscle stretching and strengthening exercises applied two sessions/week for 6 weeks. PEMF was applied with 20 Hz, 0.8 mT for 20 minutes two sessions/week for 6 weeks. Pain level was measured by visual analog scale (VAS) and neck functions were measured by neck disability index (NDI). The level of significance was set at p< 0.05.

Results: Wilcoxon matched-pairs signed-ranks test revealed significant differences in VAS and NDI in PEMF+EX and PL+EX groups (p <0.0001). Mann-Whitney (MW) Test showed significant decreased in VAS and NDI scores both treatment (p <0.0001) with more significant decrease in PEMF group than PL+EX group.

Conclusion: PEMF combined with exercise was effective more than exercises alone in decreasing the scores of VAS and NDI in Chronic MNP.

KEY WORDS: Chronic MNP, Exercise, Neck disability index, Pain, Pulsed electromagnetic field.

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Access this Article online						
Quick Response code	International Journal of Physiotherapy and Research ISSN 2321- 1822 www.ijmhr.org/ijpr.html					
DOI: 10.16965/ijpr.2017.105	Received: 10-01-2017 Peer Review: 11-01-2017 Revised: None	Accepted: 09-02-2017 Published (O): 11-04-2017 Published (P): 11-04-2017				

INTRODUCTION

Mechanical neck pain (MNP) is a common neck disorders. The patient feel pain between the neck and shoulder regions starting from the nuchal line to the first thoracic spinous process [1] accompanied by local area of tenderness and limitation in the cervical range of motion (ROM) [2]. MNP is common affecting 30% to 50% of the middle aged population [3]. Bad neck postures, neck movement, or palpation of the neck region may provoked pain [4]. MNP causing severe discomfort affect patient's daily life and ability to work [5,6]. It is characterized by structures and functional features within the cervical spine when it persisted, it is developed into chronic MNP [7-9].

The exact cause of chronic MNP is not completely clear [5]. In addition to psychosocial stress, the existence of mechanical factors like prolonged use of computers, maintaining faulty posture for prolonged time and repetitive movements may contribute to the development of chronic MNP [10,11].

The treatment of chronic MNP includes pharmacological [12] and non-pharmacological interventions. The non-pharmacological treatment may include manual therapy [13], massage [14] and neck exercises [13]. The American Food and Drug Administration (FDA) permit the use of PEMF as a modality for treatment of pain [15]. There is increasing evidences for using magnetic fields for treatment of chronic musculoskeletal pain, muscle soreness and neuropathy [16]. Many studies investigated the effect of either static magnet or pulsed electromagnetic field (PEMF) on chronic pain in rheumatoid arthritis, fibromyalgia [17] and lumbar spondylosis [18] as well as in pain and stiffness associated with delayed onset muscle soreness [19] or in postoperative pain [20]. While the researchers reported significant decreased in pain score [17,18], others reported lack of efficacy in controlling pain, improving performance of soccer-specific fitness performance test performance [21] or recovery of delayed onset muscle soreness [19].

For the available literature, with the lack of evidences supporting the use of PEMF as one of physical therapy interventions used in the treat ment of patient with chronic MNP, therefore the aim of this study was to investigate the effect of PEMF on pain and functional improvement in chronic MNP.

SUBJECTS AND METHODS

This study design was a randomized controlled trial. In order to examine the effect of PEMF on chronic MNP, patients were randomized into two groups. Group one received PEMF plus exercises (PEMF+EX) and group two received Placebo PEMF plus exercises (PL+ EX). The University's Ethics in Research Committee (local registry number 43409007), Umm Al-Qura University, approved the study. The study has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

To calculate number of patients, a preliminary power analysis was done by G-power program for windows with 0.05α probability error, 0.80 power (1- β error probability), using t east to calculate the difference between two independent means (two groups) with allocation ratio of patients to two groups was 1:1. The effect size chosen was based on a pilot study of changing in pain score (from 7 to 3.2 ± 1.5) measured by visual analogue scale (VAS) with r = 0.80 and Cohen's d = -2.71. The estimated sample size was 52 patients for both groups. A number was increased to 30 patients in each groups for possible dropout.

Patients were recruited from AL-Noor hospital, Mecca, Saudi Arabia. Treatment of All patients was done at Physical Therapy department, Faculty of Applied Medical Science, Mecca Saudi Arabia. A rheumatologist examined patients before a decision was made to include them in the study. Patients with their age from 20 to 30 years were included in the study if they had chronic MNP for at least 3 months' duration. Pain with local area of tenderness was allocated in the neck, shoulders and/or inter-scapular area at rest or at neck movements. The patients did not take any anti-inflammatory, analgesic and muscle relaxant drugs through the course of the study.

The patients were excluded if they had a referred pain to upper arm or with a positive motor,

reflex, or sensory abnormalities indicating spinal root compression. Patients with a systemic rheumatological disease as rheumatoid arthritis and/or congenital malformation, trauma, cerebrovascular abnormalities, previous cervical spine surgery or stenosis were also excluded in the study.

After baseline evaluation, patients were selected to participate in the study by give them numbers from 1 to 60. Patients were randomized into two groups by random number generator using graph Pad on web. The patients were volunteered to participate in the study. A full explanation was given to all patients about nature of the study and the course of treatment, which consists of 12 treatments sessions, given twice a week for 6 weeks. All Patients signed a written informed consent included their agreement for participation in the study. An exercise handout was given to every patient that included the exercises program.

Assessment of pain: A visual analogue scale (VAS) is an ordinal scale, using a 10-cm line divided into 10 equal sections, with 10 representing "unbearable pain" and 0 representing "no pain". For all patients, VAS was used for the assessment of neck pain [22]. Each patient was asked to indicate on the scale the level of pain in the neck at the baseline and post treatment after the end of sessions.

Assessment of neck functions: A neck disability index (NDI) was used for the assessment for neck function status [23]. The NDI is considered as valid and reliable measurement tool in patients with neck pain [24]. The NDI composed of items which measure self-perceived disability from neck pain. Each item was recorded out of 5 for a total score of 50 [25]. Each question has six answers from 0 to 5, and the patient make a mark in each section, which most closely described their problem. An Arabic version of the NDI was used for all patients. Each patient was asked to fill the index at the baseline and post treatment at the end of treatment sessions.

INTERVENTION PROTOCOLS

Pulsed electromagnetic field stimulation: Patients in PEMF group received magnetotherapy produced by the device (ASA, Arcugnano Italy). PEMF electrodes were positioned to posterior neck and upper thoracic region while the patient in supine lying position. Magnetotherapy was applied with low frequency (20 Hz), intensity of 0.8 milliTesla (mT) and time of application 20 minutes applied two sessions/ week for 6 weeks. Magnetotherapy was calibrated for constant output at the physical therapy Department, Faculty of Applied Medical Science, Umm Al-Qura University.

Patients in PL+ EX group received placebo treatment at the same interval of the active PEMF. In placebo treatment, PEMF electrodes were positioned in the same technique but there was no field during the time of treatment.

Exercises: Patients in both treatment groups received a program of exercises. Exercise program included active range of motion (ROM), muscle stretching and strengthening exercises. Active neck ROM exercise was applied in pain free range with 10 repetitions in all directions. Then patients started stretching exercises program for the upper fibers of trapezius and sternomastoid muscles. After 5 minutes rest, patients performed isometric strengthening exercises for the for the neck extensors, side bending and rotator muscles 10 times/set for three sets with 5 minutes rest in between. The same therapist performed the exercises twice a week for 6 weeks with advices to all patients to repeat the exercises at home.

Outcomes measured: Demographics like age, weight, height, and disease duration were recorded. Baseline assessment of the measured variables were performed at the beginning of the study, and performed at the last session post treatment. The measured outcomes were pain level and disability scores. Pain level was measured by VAS and neck function was measured by NDI.

Data analysis: Analysis was performed using Statistical Package for the Social Sciences (SPSS) for Windows, version 16 (SPSS Inc., Chicago, IL, USA) and Graph Pad InStat (Graph Pad Software, Inc., San Diego, CA, USA).

RESULT

A total of 60 male patients participated in this study. Both PEMF+ EX and PL + EX groups were consisted of 30 patients. Their mean age, weight, height, body mass index (BMI) and

duration of illness were 23.03 (2.239) years, 63.43 (5.195) Kg, 1.662 (5.1092) cm, 22.98 (1.879) Kg/m², 4.483(1.228) months respectively. Testing for homogeneity of variance was performed by two-sample Kolmogorov–Smirnov normality test and it revealed that the baseline mean values passing a normality test with a non-significant difference in baseline mean values (p> 0.01). Also, there were no significant differences between both treatment groups in their mean age, weight, height, BMI and duration of illness as shown in Table 1.

Table 1: Demographic characteristics of patients in bothtreatment groups.

	PEMF (mean ± SD)	PL+EX (mean ± SD)	P value
Age	22.6± 2.14	23.47± 2.29	0.1352 ^c
Weight	64.03± 5.14	62.83 ± 5.27	0.3756 ^c
Height	166.73 ± 4.92	165.7± 5.33	0.4382 ^c
BMI (Kg/m ²)	23.067± 2.014	22.896± 1.765	0.7268 ^c
Duration of illness	4.367± 1.189	4.6±1.276	0.4665 ^c

BMI: body mass index, **SD:** Standard deviation **c:** Non-significant changes

Table 2: Changes of VAS and NDI in both treatment groups.

	VAS			NDI		
	PEMF	PL+EX	P value	PEMF	PL+EX	p value
Pre	7.967 ±0.81	8.067 ± 0.78	0.6872 ^c	44.77±5.41	45.63± 4.43	0.6238 ^c
Post	2.17± 0.91	3.033 ± 0.67	0.0004 ^a	7.63± 1.77	11.53 ± 1.55	< 0.0001 ^a
p value	< 0.0001 ^b	< 0.0001 ^b		< 0.0001 ^b	< 0.0001 ^b	
Cohen effect size d	1.08, CI(0.538 - 1.622)			2.344, CI(1.687 - 3.002)		1

VAS: Visual analogue scale; **NDI**: Neck Disability Index; CI: Confidence interval.

a: Significant differences between treatment groups; Mann Whitney test, p > 0.05

b: Significant differences in each treatment group;
Wilcoxon matched-pairs signed-ranks test, p > 0.05
c: Non-significant differences.

Mann-Whitney (MW) Test was used to compare between baseline values of VAS and NDI scores in both treatment groups. It showed non-significant differences as shown in table 2. Comparing between both treatment groups in post treatment VAS and NDI scores showed significant differences as shown in table 2. Wilcoxon matched-pairs signed-ranks test was used to compare between the baseline and post treatment values of VAS and NDI scores. It revealed significant differences in both VAS and NDI in both PEMF+EX and PL+EX groups (Table 2). Values of VAS and NDI at post treatment decreased PEMF group more than PL+EX group. Cohen effect size was calculated to compare the changes in PEMF+EX to that of PL+EX and reveled a moderate effect size of VAS and NDI as shown in Table 2.

DISCUSSION

This study was conducted to investigate the effect of PEMF in combination with exercises on pain and neck functions in patients with chronic MNP. The finding in the current study was that PEMF combined with exercise was effective more than exercises alone in decreasing the scores of VAS and NDI after 6 weeks of treatment.

Magnetic therapy has a long history in the treatment of various medical conditions to improve the recovery of various health problems [26]. Doctors from Greece, China, Japan, and Europe successfully used the magnet in their practice to treat patients [15]. Nowadays,magnetothe rapy is considered as a safe, easy and noninvasive physical therapy modality used to treat pain, inflammation and other types of pathologies and diseases [15].

Magnetic therapy can be applied in different modes. It may be continuous magnetic fields, low-frequency sinusoidal waves, PEMF and transcranial magnetic stimulation [27]. Researchers used many forms of small magnet or large magnetic equipment with a major claim given by researchers to the effect of these magnetic products to be considered as pain relieving modality [20,21,19] as in low back pain [28], heel pain [29] and muscle pain [30].

On the other hand, researchers used the transcranial magnetic stimulation for the treatment of depression [31] or use the small magnet to stimulate the trigger point [32]. The result found significant effect of magnetic stimulation for relief of pain. Studies showed that pulsed, low frequency sinusoidal magnetic fields have been shown to alter pain perception and affect thermal sensory and pain thresholds in patients with rheumatoid arthritis and fibromyalgia. [33,17].

Despite the increasing popularity of magnetic therapy, there is a relatively little number of the available researches which discuss the efficacy of magnetotherapy and its use [34]. Although PEMF is considered as a pain relief modality,

the underlying mechanisms remain unclear [35]. Researchers attempt to explain the mechanism of action as PEMF causes flow of electrical charges which in turn causing a flow of ionic current necessary for restoration of basic cellular activities and the stimulation of growth factor [36]. Another explanation that describe the mechanisms of action of magnetic therapy is through the magnetic induction, magnetomechanical effects and electronic interactions with cellular functions and is responsible for the increasing blood flow, reducing pain, antiinflammatory, anti-edematous and spasmolytic activity and healing acceleration [37].

Magnetotherapy increased the local blood flow which may speed tissue recovery and cause pain relief [27]. It may also alter the body fluids pH, increase the enzyme activity and pain thresholds in free nerve endings [38]. Moreover, researches suggested that PEMF decrease pain and restricted spinal mobility [39,18], relieve the myofascial pain [40] and effectively reduce cervical spondylotic pain [41].

The results of the present study showed that there was a significant difference between both groups regarding pain level and neck functions. It could be postulated that PEMF had analgesic effect as shown in the PEMF group. Because the MNP was chronic lasting for long duration before therapy, the improvement could not be spontaneous recovery. In addition, the study had control group which get placebo FEMF and exercises and they show no such improvement as in the PEMF group who receive active PEMF. That may exclude the possible effect of placebo treatment.

CONCLUSION

It was concluding that the PEMF stimulation combined with exercises was more effective than exercises alone in the treatment of patients with chronic MNP.

Recommendation: Magnetotherapy is a physical therapy modality that could be used in combination with exercises in the treatment of patients with chronic MNP for better outcomes.

Limitations: The patients were recruited from the male section of the rehabilitation department in the hospital, and therefore all patients

were male. All patients were instructed to perform exercises at home, and a report of exercise compliance was obtained from family members. Despite neither the family members nor the participants themselves reporting any deficiency in the exercise prescription at home, we considered this to be a limiting factor in the present study.

Funding: This research received no specific grant from any funding agency in the public, commercial, or non-profit sectors.

ACKNOWLEDGEMENTS

The authors express their appreciation to all subjects who participated in this study with all content and cooperation, and give special thanks to their colleagues at the Department of Physical Therapy, Faculty of Applied Medical Science, Umm AL-Qura University, Saudi Arabia.

Conflicts of interest: None

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How to cite this article:

Mohamed Salaheldien Alayat, Mohamed Mohamed Ibrahim Ali, Amir Abdel Raouf El Fiky, Mansour Abdullah Alshehri. EFFICACY OF PULSED ELECTROMAGNETIC FIELD ON PAIN AND FUNCTION IN CHRONIC MECHANICAL NECK PAIN: A RANDOMIZED CONTROLLED TRIAL. Int J Physiother Res 2017;5(2):1930-1936. **DOI:** 10.16965/ijpr.2017.105