Pulsed Magnetic Field Therapy in Carpal Tunnel Syndrome: A Randomized, Placebo Controlled Double-Blind Study

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ABSTRACT

This study investigated the efficacy of pulsed magnetic fields therapy (PMFT) at different frequencies in patients with carpal tunnel syndrome (CTS) in a randomized, placebo-controlled, double-blind study. Forty five female patients (60 hands) diagnosed as mild to moderate CTS were included in the study. Their ages were 38: 57 years with mean age 49 ± 3.5 years. Patients were divided randomly into three equal groups, placebo group received sham exposure, and two magnetic groups received active exposure. The two magnetic groups were magnetic group I, received PMFT at frequency of 50 Hz and magnetic group II, received PMFT with a frequency of 5 Hz. The outcome measurements were median nerve sensory distal latency (SDL), motor distal latency (MDL) and Boston carpal tunnel syndrome questionnaire (BCTQ). Measurements were carried out at baseline and two months later. Paired analysis for comparison between pre and post treatment measurements in each group showed significant decrease of SDL and MDL and BCTSQ scores of both magnetically treated groups. In contrast, there was non significant increase of any variable in the placebo-treated group. In respect to all outcome measure, baseline assessments showed that the studied groups were equally matched. While after treatment there were significant decreases of all measurements of both magnetic groups than placebo group and significant decrease that of magnetic group I than magnetic group II. The results suggested that the PMFT at a frequency of 50 Hz might be beneficial in improving median nerve electrophysiological function and reducing disability in patients with CTS. Furthermore, the choice of the right frequency for optimum effect of magnetic therapy should be considered.

Key words: *Magnetic therapy, Carpal tunnel syndrome.*

INTRODUCTION

Carpal tunnel syndrome (CTS) involves entrapment of median nerve at the wrist. Median nerve compression was suggested to result mainly from increase in the pressure of the carpal tunnel which affects nerve circulation leading to impaired nerve axonal transport with neurogenic symptoms. Clinically, patients are presented with paraesthesia, numbness and tingling in the distribution of the median nerve. With the progression of the disease, weakness and atrophy of the theaner muscle occurs[1,9].

Treatment of carpal tunnel is categorized into nonsurgical[19] and surgical treatment[6]. Conservative nonsurgical treatment is usually effective in the early stages with mild to moderate CTS. It includes nonsteroidal anti-inflammatory drugs[19], splinting[7], ultrasound[20], low level laser[8] and manual therapy[2], while surgical approach is considered in sever CTS when conservative approach failed[6].

Trials of alternative modalities for treatment of CTS are introduced as magnetic therapy [24-28]. In the last few years, there is an increasing interest in the use of pulsed magnetic field in alternative and complementary medicine[22]. The beneficial effects of low intensity pulsed magnetic field (PMF) on different biological functions have been reported[11,17]. It was demonstrated that pulsed magnetic field therapy (PMFT) could help in reduction of pain and resolution of inflammation of musculoskeletal system[13,18]. It also enhances wound[23] and bone healing [4], and stimulates neural tissue regeneration[12].

PMF produces its effect through influencing the ionic motion across the cell membrane thus re-establishing the normal potentials and accelerating the rate of healing of tissues. In addition PMF was proposed to induce currents in the exposed tissue which could affect excitable tissues [15,21].

Nevertheless despite the reported researches concerning the therapeutic use of PMFT to improve function of different tissue types, implementation of magnetotherapy in clinical situations remains constrained, as proposed by Markove and Colbert (2001). The authors provide the explanation that most of the studies were open trials and only a few have been done on double blinded control

studies. Furthermore, they suggested that, to optimize the effect of MFT, the correct choice of a variety of parameters such as amplitude, field frequency and shape and duration of exposure[17].

Concerning the efficacy of magnetic field on decreasing neuropathic pain and improving nerve function in CTS, up to our knowledge, all the reported researches using either static[24,26] or pulsed magnetic field[27,28] were pilot studies conducted in refractory carpal tunnel syndrome. The results of those studies were promising and they suggested future studies using randomized controlled design and they added that if the results of the future studies were positive, it would be reasonable to consider implementing magnetic therapy as part of the conservative treatment of CTS.

Recently one randomized controlled trial investigated the effect of combined static and pulsed magnetic field on CTS and reported improvement of both clinical and electrophysiological function[11].

From all that have been reviewed, it is clear that we are in need to well designed researches to clarify and establish the effect of magnetic therapy with the optimal parameters in CTS. So the current randomized, placebo-controlled, double-blind study was conducted to determine the effect of PMFT with different frequencies in CTS.

MATERIALS AND METHODS

Subjects

A total of 45 female patients with 60 hands (bilateral in 15 patients) were included in the study. Their ages were 38: 57 years with mean age 49 ± 3.5 year. All patients were diagnosed as mild and moderate CTS by clinical examination and electrodiagnostic tests. Patients had been complaining for at least 6 months to two years. They were recruited from the outpatient clinic of the Faculty of Physical Therapy, Cairo University and outpatient clinic of Kaser El-Eini Hospital. Subjects were enrolled if they had neuropathic symptoms of numbness, tingling or burning pain in the territory of the median nerve at the hand, positive Tinel or Phalen signs[1] and supported by the presence of abnormal electrodiagnostic finding including median nerve sensory distal latency (SDL) > 3.7 msec and motor distal latency (MDL) > 4.0 msec[5]. The exclusion criteria were cervical radiculopathy, thoracic outlet syndrome, and patients with other predisposing etiology as diabetes mellitus and pregnancy.

Study Design

This was randomized, placebo-controlled, double-blind study. Patients were randomly assigned into 3 equal groups each containing 20 hands. (placebo group, magnetic group I, and magnetic group II). Randomization was allocated using the numbered envelops method. Subjects were blinded about which group they were allocated.

Testing Procedures

Measurements included electro-diagnostic studies and functional assessment. Measurements were conducted at the beginning of the study and after two months at termination of the treatment. Measurements were conducted by an assessor who was blinded about subject group allocation.

Electrodiagnostic testing

Electrodiagnosis included median nerve sensory distal latency (SDL) and motor distal latency (MDL)[3]. All tests were conducted in the Electrophysiological Lab at the Faculty of Physical Therapy, Cairo University using Tonnies neuroscreen plus EMG apparatus.

Before testing, for all patients several steps of preparation were conducted. The skin under the recording and stimulating electrodes was cleaned with alcohol and conducting gel was put under the recording electrodes. The room temperature was kept at 22 ˚C.

- For measurement of orthodromic SDL, the recording electrode in the form of bar electrode was placed near the proximal wrist crease at the volar aspect of the wrist, the stimulating electrodes consisted of ring electrodes placed around the proximal and distal interphalangeal joints of the second digit. The earth electrode was fastened on the dorsum of the hand at the wrist joint.
- For measurement of MDL of the median nerve, two recording electrodes were placed over the abductor pollicis brevis. For standardization, the active recording electrode was placed halfway between the

first carpometacarpal joint and metacarpophalangeal joint of the thumb while the reference electrode on the tip of the thumb. The stimulating electrode was placed on the volar aspect of the wrist between tendons of the flexor carpi radialis and Palmaris longus muscle. The ground electrode was fastened on the dorsum of the hand at the wrist joint.

For testing the sweep speed was set at 30 msec, the sensitivity was 4000.0 uV/ Div and the duration of the stimulus was 0.1 msec. the intensity was increased until action potentials reached maximal amplitude and then the latency was recorded.

Functional Assessment

The functional level of the patients were determine using Boston carpal tunnel syndrome questionnaire (BCTQ) which was reported to be reliable and valid[14]. The questionnaire included two scales, symptoms severity scale (SSS) including 11 questions about neurogenic symptoms as pain severity and frequency, paresthesia, numbness and weakness. The second part is the functional status scale (FSS) including 8 items covering daily activities commonly affected by CTS. The patients rated their symptoms and their rate to perform activities on a scale of 1 (mildest symptoms or no difficulty with activity) to 5 (sever symptoms or can not perform the activity at all). Then the mean of the scores for each scale was calculated.

Treatment Procedures

Each subject in the two magnetic groups exposed to pulsed magnetic field therapy while subjects in the placebo group received sham exposure. Magnetic field exposure was delivered using ASA magnetic field apparatus (PTM Quattro Pro- Venice- Italy). The treatment regime consisted of 5 days / week for two months.

Subjects in magnetic group I exposed to magnetic field over the area of the median nerve at the wrist and forearm with frequency 50Hz, intensity 20 gauss, and for duration of 30 minutes. While subjects in magnetic group II exposed to a magnetic field with frequency 5Hz, intensity 20 gauss, for 30 minutes duration.

Subjects in all groups were allowed to receive their routine medications of vitamin B6, a dose of oral analgesic (Ibuprofen 800mg twice a day) [19].

Data Analysis

Statistical analysis was performed using "SPSS" for windows evaluation version 15.0. Descriptive statistics in the form of mean, standard deviation and percentage of improvement of the SDL, MDL and scores of BCTQ pre and post treatment were calculated. Paired t test comparing pre and post measurements was performed for individual group. ANOVA test was performed for each variable comparing the three groups at pre and post treatment. Post –hoc test was then used to determine differences between each two group. Significance level was set at (0.05).

RESULTS

Electrophysiological parameters

As shown in table (1and 2), when comparing pre and post measurements using paired t-test, there were significant decrease of SDL and MDL in both magnetic groups, while there was non significant increase in the placebo group. The highest percent of improvement was recorded in the magnetic group I (13.3% in SDL and 16.98% in MDL) while in the magnetic group II were (8.51% in SDL and 9.8% in MDL).

Table (1): Sensory distal latency (msec) pre and post treatment of the three groups.

	Placebo group		Magnetic I group		Magnetic II group	
	Pre	Post	Pre	Post	Pre	Post
Mean	4.6	4.7	4.5	3.9	4.7	4.3
SD	0.09	0.37	0.88	0.65	0.26	0.67
% Diff	2.1 %		-13.3 %		-8.51 %	
t	1.56		7.8		3.2	
P	0.13		< 0.000*		0.00l*	

SD: Standard deviation, % diff: percentage of difference, * significant

Table (2): Motor distal latency (msec) pre and post treatment of the three groups.

	Placebo group		Magnetic I group		Magnetic II group	
	Pre	Post	Pre	Post	Pre	Post
Mean	5.2	5.3	5.3	4.4	5.1	4.6
SD	0.45	0.77	0.89	0.47	0.09	0.62
% Diff	1.9 %		-16.98 %		-9.8 %	
t	1.45		9.3		2.87	
P	0.1		< 0.000*		0.04*	

SD: Standard deviation, % diff: percentage of difference, * significant

For determining the differences among the three groups in median nerve SDL and MDL, ANOVA test revealed that there were non significant difference at pre measurements and significant difference at post treatment measurement (P < 0.000), table (3).

Table (3): ANOVA test results for comparisons among the three groups at pre and post treatment.

	Pre		Post	
	F	P	F	P
SDL	1.4	0.3	12.5	< 0.000*
MDL	1.5	0.1	9.8	< 0.000*
BCTQ	0.3	0.7	10.4	< 0.000*

SDL: sensory distal latency, MDL: motor distal latency, BCTQ: Boston carpal tunnel syndrome questionnaire, *: significant

Table (4) represented the results of post hoc test for comparison between each two groups at post treatment and showed that, compared to placebo group there were significant improvement of SDL and MDL of magnetic group I than placebo group (P< 0.000). Also there were significant improvement of magnetic group II than placebo (P= 0.007, and 0.02) respectively. Furthermore there was significant improvement of that of magnetic group I than magnetic group II where P was <0.000 for SDL and MDL.

Table (4): Post Hoc comparisons of the tested parameters at post treatment.

	SDL		MDL		BCTQ	
	t	P	t	P	t	P
Placebo Vs magnetic I	7.8	< 0.000*	10.3	< 0.000*	12.1	< 0.000*
Placebo Vs Magnetic II	3.7	0.007*	2.25	0.02*	2.8	0.003*
Magnetic I Vs Magnetic II	8.9	< 0.000*	9.7	< 0.000*	10.3	< 0.000*

SDL: sensory distal latency, MDL: motor distal latency, BCTQ: Boston carpal tunnel syndrome questionnaire, *: significant

Boston CTS questionnaire scores

As presented in table (5) there was significant decrease in the scores of the BCTQ of both magnetic groups denoting improving of symptoms and function (P< 0.000 in magnetic group I and 0.001 in magnetic group II). While, there was non significant changes of that of the placebo group.

When calculating the percentage of difference as compared to the pre scores, the magnetic group I showed 35.18 % and the decrease in magnetic group II was 22.41 %, while the placebo group showed 7.14 % increase in the scores denoting deterioration of symptoms and function.

Table (5): Boston CTS Questionnaire scores pre and post treatment of the three groups.

	Placebo group		Magnetic I group		Magnetic II group	
	Pre	Post	Pre	Post	Pre	Post
Mean	5.6	6	5.4	3.5	5.8	4.5
SD	0.7	0.6	0.6	0.9	0.7	0.7
% Diff	7.14 %		35.18%		22.41 %	
T	0.2		12.3		3.2	
P	0.81		< 0.000*		0.001*	

SD: Standard deviation, % diff : percentage of difference, * : significant

The results of the ANOVA test presented in table (3) showed that there was no significant difference of the pre test scores of BCTQ among the three groups (P= 0.7). But, there was significant difference in the post test scores among the three groups (P <0.000) table 3. The results of the post hoc test showed that compared to the placebo group, there were significant decrease in the scores of the BCTQ of magnetic group I (P<0.000) and magnetic group II (P= 0.003). When comparing both magnetic groups, there was significant decrease in BCTQ of magnetic group I than those of magnetic group II (P <0.000) table4.

DISCUSSION

CTS is a common upper extremity musculoskeletal disorder which occurs commonly in adults older than 30 years, particularly women and people with jobs involving repetitive hand movement[1,9].

The current study was conducted to investigate the potential effectiveness of PMFT with two different frequencies in improving neural function of the median nerve and decrease disability in patients with CTS.

The results of the study demonstrated that PMFT at both selected frequencies improved median nerve function and decreased symptoms with improvement of functional level using the affected hand. On an attempt to explain this effect, it could be attributed to the influence of PMF on ionic motion across the cell membrane causing charge transfer on the cell membrane thus enhancing cell function and neural transport across the nerve [15].

Furthermore, the current study proposed that PMF with 50 Hz produced better effects on median nerve conduction and improved hand function than PMF with 5 Hz frequency. It was reported that functional recovery after nerve crush injury is accelerated by PMFT at a frequency of 50 Hz [12]. In addition, it was postulated that exposure to PMF at a frequency between 50:60 Hz stimulated neurite growth[16]. Also PMF was found to influence axonal growth and promote nerve regeneration[29].

Regarding the improvement of the neural function and BCTQ scores of the magnetic group II which received PMFT at 5 Hz, it was reported that PMFT could decrease neuropathic pain in subjects with CTS and polyneuropathy[24,26,29]. But up to our knowledge and the review of literature, no study comparing and investigating the effect of frequency of PMF in CTS. So in the present study, we chose two frequencies of PMF which were reported to be effective in treatment of CTS and compared between them.

This study was designed as placebo controlled double blind study. Nowadays, there is much attention towards evidenced based practice. Although PMF has at last received worldwide recognition, most of the researches work done on the effect of PMF on biological function were pilot studies or a research report with the recommended need for conducting a well designed study[27,28]. This study showed the feasibility of recruiting and retaining compliant participants for a randomized controlled study. For ethical considerations, patients in the sham group after termination of the study and outside of the study, received physical therapy program for two additional months.

In the current study we use BCTQ to evaluate the patient progress regarding neurogenic symptoms and functional activities. That is why we not include any other measures for pain as it is already covered by the questionnaire. This questionnaire is considered as validated self-administered questionnaire[14]. The present study demonstrated higher percent of improvement of symptoms and function as presented in BCTQ (35.18 and 22.41%) than the percent of improvement in the neurophysiological function of median nerve as presented in SDL (13.3% and 8.51%) and MDL (16.98% and 9.8%). The explanation might be that beside direct effects of PMF on neural tissues, PMF was reported to affect the distribution of ions across the across the cell membrane thus accelerates the re-establishment of normal potentials and accelerates the rate of healing [11]. Also through the mechanism of magnetohydrodynamics, PMF was proposed to improve blood supply to the tissue and increase energy utilization and turnover with rise in ATP[10]. All those effects combined with

the improvement in the neural function could lead to improvement of the overall condition of the CTS as showed in the higher percent of the BCTQ score.

Conclusion

The results of this controlled study demonstrated the efficacy of PMFT in enhancing median nerve function and decreasing neurogenic symptoms together with improving functional level of the activities involving hand in patients with CTS. Clinically, the frequency of PMF should be considered when treating patients with CTS with the suggestion of 50 Hz frequency to be utilized. Further long term studies to confirm the general efficacy and cost effectiveness of PEMF therapy in treatment of CTS are recommended. Further studies using different field intensities and treatment protocols and patient populations are warranted.

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الملخص العربى

تأثيرالعلاج بالمجال المغناطيسى المتردد على متلازمة اختناق العصب الأوسط عند الرسغ: دراسه عشوائيه، مزدوجة الإستتار بإستخدام مجموعة حاكمه

قامت هذه الدراسه بدراسة كفاءة العلاج بالمجال المغناطيسى المتردد ذو الترددات المختلفه فى مرضى متلازمة اختناق العصب الأوسط عند الرسغ من خلال دراسه عشوائيه مزدوجة الإستتار بإستخدام مجموعة حاكمه . أجريت هذه الدراسة على خمسة وأربعون سيدة(ستون يد) تم تشخيصهم كمتلازمة اختناق العصب الأوسط عند الرسغ بدرجه بسيطه. تراوحت أعمارهم بين 38 و57 عاما و متوسط أعمارهم 49± 3,5 عاما. تم تقسيم المرضى عشوائيا إلى ثلاث مجموعات متساويه ، المجموعه الحاكمه تم تعريضها الى مجال مغناطيسى متردد غير نشط ومجموعتان مغناطيسيتان تم تعريضهما الى المجال المغناطيسى المتردد النشط. المجموعه المغناطيسيه الأولى تعرضت لمجال مغناطيسى متردد ذو تردد خمسون هيرتز والمجموعه المغناطيسيه الثانيه تعرضت لمجال مغناطيسى متردد ذو تردد خمسة هيرتز. اشتملت القياسات على زمن الكمون الحسى والحركى للعصب الأوسط واستبيان بوسطن الخاص بمتلازمة اختناق العصب الأوسط عند الرسغ. تم قياس القياسات قبل التجربه وبعد شهرين . أظهرت المعالجات الإحصائية للنتائج وجود نقصان ذو دلالة إحصائية في زمن الكمون الحسى و الحركى للعصب الأوسط واستبيان بوسطن الخاص بمتلازمة اختناق العصب الأوسط عند الرسغ فى المجموعتان المغناطيسيتان بينما كان هناك ذيادة ليست ذات دلالة إحصائية في اى من القياسات و بالمقارنة بين الثلاث مجموعات' لم يكن هناك فروق ذات دلاله إحصائيه فى اى من القياسات الأوليه عند بداية التجربه . بينما عند نهاية العلاج وجدت فروق ذات دلاله إحصائيه المجموعتان المغناطيسيتان عنه في المجموعة الضابطه ووجود تحسن ذو دلالة إحصائية في المجموعة المغناطيسيه الأولى عنه في المجموعة المغناطيسيه الثانية. أثبتت هذه الدراسه ان العلاج بالمجال المغناطيسى المتردد ذو تردد خمسون هيرتز يمكن ان يحسن الوظائف الكهروفيسيولوجيه للعصب الأوسط و يقلل الاصابه فى مرضى متلازمة اختناق العصب الأوسط عند الرسغ. بالإضافه إلى ذلك يجب مراعاة اختيار أفضل تردد للمجال المغناطيسى للحصول على أحسن تأثير.