

The Effectiveness of Pulsed Magnetic Field Therapy in Idiopathic Carpal Tunnel Syndrome: A Randomized, Double Blind, Sham Controlled Trial

İdiyopatik Karpal Tünel Sendromlu Hastalarda Pulse Manyetik Alan Tedavisinin Etkinliği: Randomize, Çift Kör, Kontrollü Çalışma

Firdevs Arkan, Aysel Yıldız, Nur Kesiktaş, Ayşe Karan, Semih Akı, Lutfiye Muslumanoğlu
Istanbul University, Istanbul Medical Faculty, Physical Medicine and Rehabilitation Department, Istanbul, Turkey

ABSTRACT

Conservative treatment approaches are primarily focused on the therapy of carpal tunnel syndrome (CTS). Pulse magnetic field therapy (PMFT) is one of the conservative method for CTS. In this randomized, double-blind, 'sham' controlled trial, PMFT's effectiveness to clinical and electrophysiological parameters on the patients with idiopathic CTS was studied. Among 38 patients (57hands) who had the inclusion criteria, 36 of them(53hands) completed the study. Enrolled patients were randomized 1:1 methodology into two groups by physiotherapist, applied to 18 of the patients (27hands) with PMFT and sham with 20 of them (30 hands) were treated. Each patient was evaluated with clinical and electrophysiological parameters before and after the treatment and one month later after treatment. Clinical parameters were the awakening scores due to pain, evaluation of the pain with visual analogue scala (VAS) and symptom severity score. Electrophysiological parameters were median sensory distal latency, amplitude and the velocity of sensory nerve conduction, motor distal latency, amplitude and velocity of motor nerve conduction. In statistical analysis, student t-test,chi square test, Mann-Whitney U and Wilcoxon test were carried out by using SPSS 10.1 computer program. As a result of these tests, it was observed that both two treatments have influences on clinical and electrophysiological variables at the end of the therapy and one month later after the therapy, however PMFT is not superior to sham according to clinical and electrophysiological findings. In these terms, PMFT seems ineffective in idiopathic CTS; besides we consider it is essential to follow up in a long. (*J PMR Sci 2011;14:1-8*)

Keywords: Idiopathic carpal tunnel syndrome, magnetic field therapy, nerve conduction

ÖZET

Karpal Tünel Sendromu (KTS) tedavisinde öncelikle konservatif tedavi yaklaşımlarına odaklanılır. Pulse manyetik alan tedavisi (PMAT) KTS için konservatif yöntemlerden biridir. Bu randomize, plasebo kontrollü, çift kör çalışmada idiopatik karpal tünel sendromlu hastalarda pulse manyetik alan tedavisinin klinik ve elektrofizyolojik parametrelere etkinliği araştırıldı. Yöntem Alınma kriterlerini taşıyan 38 hastanın (57 elin) 36'sı (53 el) çalışmayı tamamladı. Fizyoterapist tarafından 1:1 randomize edilen hastaların 18'i (27 el) pulse manyetik alan 20'si de

Corresponding Author Yazışma Adresi

Nur Kesiktaş
Istanbul University, Istanbul Medical
Faculty, Physical Medicine and
Rehabilitation, Istanbul, Turkey
E-mail: nur.kesiktaş@gmail.com

Received/Geliş Tarihi: 01.12.2010
Accepted/Kabul Tarihi: 28.03.2011

(30 el) plasebo manyetik alan tedavisi gördü Her hasta tedavi öncesinde, sonrasında ve tedaviden 1 ay sonra klinik ve elektrofizyolojik son noktalarla değerlendirildi. Klinik son noktalar VAS, semptom skoru ve ağrı nedeniyle uyanma skorundan oluşurken elektrofizyolojik son noktalar median duyuşal distal latans, duyuşal amplitüd, duyuşal sinir ileti hızı, motor distal latans, motor amplitüd ve motor sinir ileti hızını içeriyordu. İstatistik analizlerde, SPSS 10.1 bilgisayar programı kullanılarak student t-test, chi-square test, Mann-Whitney U Wilcoxon test uygulandı. Bu testlerin sonucu olarak, her iki tedavinin, tedavi sonrası ve tedaviden 1 ay sonra klinik ve elektrofizyolojik son noktalar etkin olduğu, ancak pulse manyetik alan tedavisinin klinik ve elektrofizyolojik olarak plaseboya üstün olmadığı görüldü. Bu çalışmanın takip süresi ve çalışılan el sayısı göz önüne alındığında daha sağlıklı sonuçlar elde etmek için fazla sayıda ve uzun dönem takipleri olan hastalarla çalışmanın gerekli olduğu ortaya çıkmaktadır. (FTR Bil Der 2011;14:1-8)

Anahtar kelimeler: İdyopatik karpal tünel sendromu, manyetik alan tedavisi, sinir iletileri

Introduction

Entrapment neuropathies are called that become as a consequence of peripheral nerves's compression during anatomic distribution. Carpal Tunnel Syndrome (CTS), caused by compression of median nerve at the wrist, is considered the most common entrapment neuropathy. Although a variety of conditions may be associated with CTS, the cause is unknown for up to 50% of patients and is diagnosed as "idiopathic carpal tunnel syndrome"(1-4).

Conservative treatment approaches are primarily focused on CTS therapy (5). There are few studies concerning the use of magnetic field therapy in CTS (6). The mechanism most commonly offered for various therapeutic effects of magnetic field therapy is improved blood circulation. Other suggestions include alteration of nerve impulses, increased oxygen content and increased alkalinity of bodily fluids, magnetic forces on moving ions, and decreased deposits in the vessel walls (7).

The main purpose of this study is to determine the efficacy of Pulsed Magnetic Field Therapy (PMFT) on clinical and electrophysiological parameters of the patients with idiopathic carpal tunnel syndrome.

Material and Method

Study Population

A total of 59 (93 hands) clinically suspected CTS patients were screened from the outpatient of Physical Medicine and Rehabilitation department at our faculty and all of them were examined for the eligibility to participate in this study by one of the participating physician. Twelve patients did not meet inclusion criteria, 7 refused to participate, 2 of them met exclusion criteria. Thirty-eight patients (57 hands) were enrolled in the study (Figure 1).

Inclusion criteria were 1) numbness, tingling or symptoms of pain in the hand; 2) diagnosis based on Quality Standards Subcommittee of the American Academy of Neurology's criteria (8), (history, physical examination, Tinel and Phalen tests); 3) electrophysiological confirmation of diagnosis as idiopathic carpal tunnel syndrome (median ulnar sensory distal latency difference of the ring finger ≥ 0.5 ms, median nerve sensory distal latency ≥ 3.3 ms, median nerve distal motor latency ≥ 4.2 ms) (9,10); 4) no spontaneous activity or markedly reduced firing frequency from the abductor pollicis brevis (APB) muscle by electromyographic examination.

Exclusion criteria were 1) symptoms shorter than 3 months; 2) previous medical and physical therapy during the last month; 3)

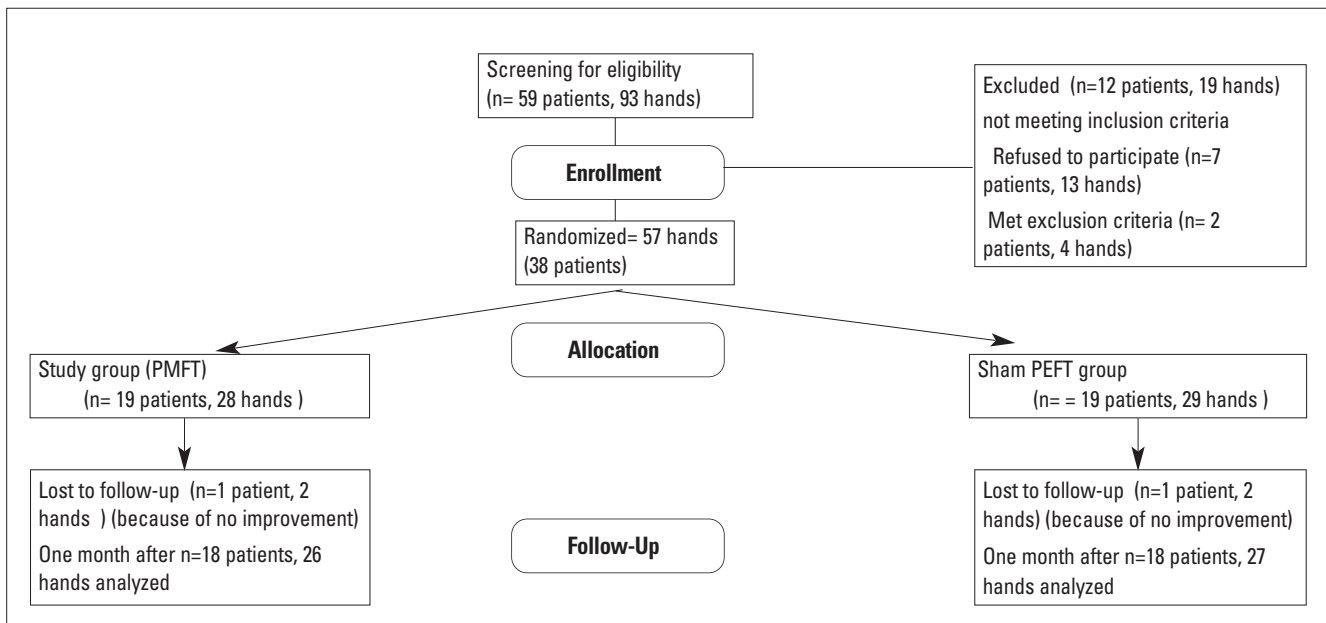


Figure 1. Patient flowchart

steroid injections to the wrist; 4) history of wrist trauma or surgery; 5) a history suggesting underlying causes of CTS (eg, diabetes mellitus or pregnancy); 6) clinical signs or symptoms or electrophysiological findings suggesting conditions that could mimic CTS or interfere with its validation (eg. cervical neuropathy); 7) being involuntary for participation; 8) serious medical problems which cause difficulties during electrophysiological study (eg. severe cardiorespiratory, mental problems); 9) severe thenar muscle atrophy; 10) contraindications for magnetic field therapy (eg. cardiac pace makers); 11) obligation for steroid and nonsteroid anti-inflamatuar drug therapy.

Randomisation

After the 57 hands (19 bilateral, 19 unilateral) of 38 eligible patients (34 female, 4 male) had been enrolled, a physiotherapist not involved in treatment allocated the each consecutive patient to magnetic field or sham treatment in 1: 1 randomisation (active and sham groups). The patient's both wrists received the same treatment. This therapist was the only person aware of the treatment allocation during the trial.

Blinding

The patients, investigator and magnetic field therapists who delivered treatment were all unaware of the treatment allocation. Only the therapist who was in charge of group allocation switched the magnetic field device to the respective modes before each therapy session.

Intervention

Each patient was informed about CTS and ergonomic precautions before the trial. They were allowed to use just paracetamol as pain killer and managed no extra treatment for CTS except planned trial.

Pulsed Magnetic Field Therapy was administered to the area over carpal tunnel as a monotherapy for 30 minutes per session, once a day for 3 weeks (totally 15 session) by using BTL-09 (ESAOTE Biomedica, Italy) two-channel magnetotherapy device with small solenoid. Affected hand/hands were located into device while neutral position. The device's private program prepared at a frequency of 25 Hz. with 11-13 mT current intensity for carpal tunnel syndrome was applied in the way that at first pulse width of 5ms and a 20 repetition (20 X 5ms) pulse then pulses width of 100ms and 40ms.

Sham therapy was carried out in the same position without running the device.

Outcome Assessments:

Assessments were done at baseline (BT), end of the therapy (AT) and a follow up assessment 1 month later (1ML) by a physician who examined patients at baseline.

a. Visual Analog Scale (VAS): The pain intensity was assessed by means of a visual analogue scale (VAS) (6,11). Pain levels were labeled on a line in 10 categories, 10 points indicating unbearable pain and 0 no pain at all.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

b. Symptom Severity Score (12,13): Presence of symptoms at night and/or day, pain and/or paresthesia was scored as follows: 0=no symptoms (only after the treatment), 1=mild (night and diurnal paresthesias), 2=moderate symptoms (nocturnal pain) , 3= severe (nocturnal and diurnal pain)

c. Frequency of Awakening from symptoms at night per week was scored (12,13): 0=never wake up, 1=awaken 1-2 times per week, 2=3-6 times per week, 3=7 times or more

d. Electrophysiological Evaluations: Motor and sensory nerve conduction studies were performed in median and ulnar nerves by using standard techniques in all patients. These were median nerve sensory distal latency (SDL), sensory amplitude (DAmp), velocity of sensory nerve conduction (VSNC), motor distal latency (MDL), motor amplitude (MAmp), velocity of motor nerve conduction (VMNC). All electrodiagnostic tests were performed by the same physician with Esaote Phasis version 2.0, electromyography apparatus in the electrophysiology laboratory of Physical Medicine and Rehabilitation Course of the Faculty of Medicine. Compound muscle action potentials of the APB muscle were recorded, induced from supramaximal electric stimulation on the median nerve at the wrist 8 cm to recording electrode. Sensory latency and sensory nerve conduction study were done from the second digit antidromically to the wrist with a distance of 14 cm. (9,10,12,14).

Statistical Analysis

Statistical Package for the Social Sciences 10.1 software (SPSS, Chicago, IL) was used for statistical analysis. Student t-test, chi square test, Wilcoxon's test, Mann-Whitney U tests were used for analysis. Pretreatment and posttreatment measures were compared by using Wilcoxon's test and Mann-Whitney U test was used to compare the measures between groups, if standart deviations were higher than a half of mean.

Results

The demographic characteristics of patients in the two groups were shown in Table 1. There was no statistically

Table 1: Demographic characteristisc of patients

| | Pulse magnetic field (study) Mean±SD | Sham magnetic field (sham) Mean±SD | p |
|-------------------------------|---|---|----------|
| Age (year) | 49.74±5.78 | 47.87±8.74 | >0.05 |
| Symptom period Median (month) | 36 (3-240) | 12 (3-264) | >0.05 |
| Patients | 19 | 19 | >0.05 |
| Bilateralite | 9 | 10 | >0.05 |
| Number of studied hands | 28 | 29 | >0.05 |

significant difference between demographic data except gender differences. The ratio of female/male ratio was 8,5:1.

There was no difference between the two groups in clinical parameters when were compared before therapy ($p>0.05$).

The results of electrophysiologic studies in both groups were shown in Table 2. In the group of sham magnetic field, SDL was observed significantly low ($p<0.01$) and SNCV was high ($p<0.01$) at the baseline.

No side effect was observed in the both groups. However at the end of the therapy one patient from each group reported that they did not improved and they discontinued the study (Both patients' bilateral hands affected). Only 36 patients (53hands) were able to complete the study in 38 eligible patients (57hands) who participated.

The comparison of clinic parameters of active group between BT, AT and 1ML were observed in Table 3. As shown in table 3; there were statistically significant improvements in the symptom score and the score of night awakening (both of them $p<0.001$) AT. When symptom scores compared at the baseline and one month after therapy; there was still significant improvement in the active treatment group, ($p<0.05$).

In the active treatment group, electrophysiologic studies were compared between BT, AT and 1ML after therapy, results

were observed in Table 4. There were statistically significant differences in SDL and MDL ($p<0.01$), in VSNC ($p<0.001$), at the end of therapy. At the one-month follow up, it was found still statistically significant differences in SDL, MDL and VSNC ($p<0.0001$), VMNC ($p<0.05$).

In sham group, subjective symptoms were compared between BT, AT and 1ML after therapy, results were observed in Table 5. Statistically significant improvements were shown in VAS and awakening score ($p<0.01$); symptom score ($p<0.0001$). At the one month follow up, pain with VAS was still statistically significant different ($p<0.05$) and symptom score had a slight increased but there was a significant improvement according to before therapy too.

In sham group, the comparison of electrophysiologic studies BT, AT and 1ML after therapy were shown in Table 6. At the end of the therapy, SDL and MDL statistically significant decreased ($p<0.0001$), VSNC were found statistically significant high ($p<0.0001$). It was same one month later after the therapy.

When both groups were compared, no significant change was observed between the clinical parameters (Table 7).

When both groups were compared, no significant change was observed among the electrophysiologic studies (Table 8).

Table 2: Comparison of electrophysiologic studies before the therapy

| Electrophysiologic studies | | Study Mean±SD | Sham Mean±SD | P |
|---|-----------------|---------------|--------------|-------|
| Median nerve sensory conduction (2. finger) | SDL (ms) | 3.87±0.50 | 3.54±0.35 | <0.01 |
| | DAmplitude (mV) | 40.05±61.80 | 33.05±17.19 | >0.05 |
| | Median | 30.8 | 31.8 | |
| | VSNC(m/s) | 35.66±4.95 | 39.80 ±4.20 | <0.01 |
| Median nerve motor conduction (APB muscle) | MDL (ms) | 5.56±0.80 | 5.23±0.70 | >0.05 |
| | Mamp (mV) | 11.30±3.15 | 11.50±2.77 | >0.05 |
| | VMNC (m/s) | 53.55±6.36 | 53.91±4.70 | >0.05 |

APB: abductor pollicis brevis, SDL: median nerve sensory distal latency, DAmplitude: sensory amplitude, VSNC: velocity of sensory nerve conduction, MDL: motor distal latency, MAmplitude: motor amplitude, VMNC: velocity of motor nerve conduction

Table 3: The comparison of clinic parameters before, after and one month later after therapy in actively treated with pulse magnetic field

| | BT Median(Min-Max) | AT Median(Min-Max) | 1ML Median(Min-Max) | BT-AT p | BT-1ML p |
|-----|-----------------------|-----------------------|------------------------|----------------|-------------|
| VAS | 0 (0-7) | 0 (0-7) | 0 (0-9) | >0.05 >0.05 | >0.05 |
| SS | 1 (1-3) | 0 (0-2) | 0 (0-3) | <0.000 | <0.05 |
| AS | 0 (0-3) | 0 (0-3) | 0 (0-3) | <0.01 | >0.05 |

Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up
Pain with Visual analogue Scale (VAS), Symptom Score (SS), Awakening score (AS)

Table 4: The comparisons of electrophysiologic studies before, after and one month later after therapy in actively treated with pulse magnetic field

| | | BT Mean+SD Median (Min-Max) | AT Mean+SD Median (Min-Max) | 1ML Mean+SD Median (Min-Max) | BT-AT p | BT-1ML p |
|---|------------|--|--|---|--------------------|---------------------|
| Median nerve sensory conduction (2. finger) | SDL (ms) | 3.87±0.57 | 3.64±0.43 | 3.54±0.41 | <0.01 | <0.0001 |
| | DAmp (mV) | 30.8 (3.6-339.8) | 26,7 (8.2-53.2) | 26 (6.8-47.7) | >0.05 | >0.05 |
| | VSNC (m/s) | 35.65±4.95 | 38.57±4.97 | 39.99±4.63 | <0.001 | <0.0001 |
| Median nerve motor conduction (APB muscle) | MDL (ms) | 5.56 ±0.77 | 5.23±0.74 | 5.18±0.68 | <0.01 | <0.0001 |
| | Mamp (mV) | 11.3±3.1 | 11.27±2.96 | 11.41±2.69 | >0.05 | >0.05 |
| | VMNC (m/s) | 53.55±6.36 | 57.03±11.1 | 59.43±12.4 | >0.05 | <0.05 |

APB: abductor pollicis brevis, SDL: median nerve sensory distal latency, DAmp: sensory amplitude, VSNC: velocity of sensory nerve conduction, MDL: motor distal latency, MAmp: motor amplitude, VMNC: velocity of motor nerve conduction,
 Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up

Table 5: In sham group, the comparison of clinic parameters before and after therapy and at the one month follow up

| | BT Mean+SD Median (Min-Max) | AT Mean+SD Median (Min-Max) | 1ML Mean+SD Median (Min-Max) | BT-AT p | BT-1ML p |
|-----|--|--|---|--------------------|---------------------|
| VAS | 0 (0-10) | 0 (0-10) | 0 (0-10) | <0.01 | <0.05 |
| SS | 1 (1-2) | 2 (0-3) | 2 (0-3) | <0.0001 | <0.001 |
| AS | 3 (0-3) | 2 (0-2) | 2 (0-2) | <0.01 | =0.046 |

Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up
 Pain with Visual analogue Scale (VAS), Symptom Score (SS), Awakening score (AS)

Table 6: In sham group the comparison of nerve electrophysiologic studies before and after the therapy and one month later after end of the therapy

| | | BT Mean+SD Median (Min-Max) | AT Mean+SD Median (Min-Max) | 1ML Mean+SD Median (Min-Max) | BT-AT p | BT-1ML p |
|---|------------|--|--|---|--------------------|---------------------|
| Median nerve sensory conduction (2. finger) | SDL (ms) | 3.54±0.35 | 3.34±0.33 | 3.25±0.32 | <0.0001 | <0.0001 |
| | DAmp (mV) | 33.05±17.8 | 33.28±15.5 | 35.81±13.8 | >0.05 | >0.05 |
| | VSNC (m/s) | 39.80±4.20 | 42.33±4.13 | 43.38±4.20 | <0.0001 | <0.0001 |
| Median nerve motor conduction (APB muscle) | MDL (ms) | 5.23±0.69 | 4,85±0,54 | 4.70±0.49 | <0.0001 | <0.0001 |
| | Mamp (mV) | 11.50±2.77 | 12.12±2.46 | 11.51±2.97 | >0.05 | >0.05 |
| | VMNC (m/s) | 53.91±4.69 | 54.93±5.37 | 56.51±8.83 | >0.05 | >0.05 |

APB: abductor pollicis brevis, SDL: median nerve sensory distal latency, DAmp: sensory amplitude, VSNC: velocity of sensory nerve conduction, MDL: motor distal latency, MAmp: motor amplitude, VMNC: velocity of motor nerve conduction
 Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up

Table 7: The comparison of clinical parameters in both groups after and one month later

| | Active (BT-AT) | Sham (BT-AT) | p | Active (BT-1ML) | Sham (BT-1ML) | p |
|-----|----------------|--------------|-------|-----------------|---------------|-------|
| VAS | 0.96±2.62 | 1.26±2.65 | >0.05 | 0.52±3.08 | 1.25±2.90 | >0.05 |
| SS | 0.81±0.73 | 0.63±0.55 | >0.05 | 0.60±1.19 | 0.46±0.69 | >0.05 |
| AS | 0.59 ±1.08 | 0.63±1.12 | >0.05 | 0.36±1.31 | 0.42±1.13 | >0.05 |

Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up
Pain with Visual analogue Scale (VAS), Symptom Score (SS), Awakening score (AS)

Table 8: The comparison of nerve conduction studies between two groups after and one month later

| | | Active (BT-AT) | Sham (BT-AT) | p | Active BT-1ML | Sham BT-1MI | p |
|---|-----------------|---------------------------------|----------------------------------|-------|---------------|-------------|-------|
| Median nerve sensory conduction (2. finger) | SDL (ms) | 0.22±0.31 | 0.20±0.21 | >0.05 | 0.34±0.36 | 0.26±0.22 | >0.05 |
| | DAmplitude (mV) | 13.39±63.45 5.8 (-70 168.42) | -0.23±19.65 13.15 (-92 177.6) | >0.05 | 12.96±68.40 | -2.08±16.75 | >0.05 |
| | VSNC (m/s) | -2.91±2.90 | -2.53 ±3.22 | >0.05 | -4.46±4.41 | -3.40±3.65 | >0.05 |
| Median nerve motor conduction (APB muscle) | MDL (ms) | 0.32±0.52 | 0.37±0.41 | >0.05 | 0.39±0.63 | 0.52±0.45 | >0.05 |
| | MAmp (mV) | 0.03±1.87 | -0.63±2.16 | >0.05 | -0.16±1.76 | 0.27±2.17 | >0.05 |
| | VMNC(m/s) | 3.48±11.43 | 1.02±5.45 | >0.05 | 5.67±12.97 | 2.38±9.11 | >0.05 |

APB: abductor pollicis brevis, SDL: median nerve sensory distal latency, DAmplitude: sensory amplitude, VSNC: velocity of sensory nerve conduction, MDL: motor distal latency, MAmp: motor amplitude, VMNC: velocity of motor nerve conduction
Baseline (BT), End of the therapy (AT), Follow up assessment 1 month later (1ML), BT-AT: The differences between baseline and the end of the therapy, BT-1ML: The differences between baseline and 1 month later follow up

Discussion

Conservative treatment approaches suggested first choice in the management of classic CTS. If etiology is diagnosed, the reason of CTS should be treated primarily. However surgery is inevitable, if there is failure to respond to conservative treatment or progressive motor/serious sensory deficits or serious electromyography (EMG) abnormalities (8).

The most frequent preferred conservative treatments in the management of CTS are education, splinting wrist in neutral position, medical treatment, physical therapy modalities and steroid injections (12-19).

There is increasing interest in the therapeutic use of magnetic fields, stimulated in large part by recent advances in alternative and complementary medicine (20). The exact mechanism by which PMFT exhibits anti-inflammatory effect is not clearly understood, but the cell membrane is most often considered the main target for electromagnetic field signals (21).

It is known that magnetic field effects to the motility of ions such as potassium, calcium and magnesium in invitro studies and makes local changes on semi-permeable cell membranes. The membrane becomes especially permeable for calcium, which could cause effective regeneration of the muscular and nervous tissue. It causes hyperpolarization by stimulating the sodium-potassium pump on the surface of cell membrane. This

event influences the cell metabolism positively. Oxygen consumption increase in cell level, local vasodilatation effect of magnetic fields improves blood circulation, consequently adenosine triphosphate synthesis increases in cells (7, 21-25).

In this research, we investigated the therapeutic effectiveness of pulsed magnetic field therapy as a conservative agent in CTS. Subjective symptoms improved and electrophysiologic cut off had significant differences, but same findings were also found in the sham group. We tried to prevent bias with preparing double blind design of study.

Various questionnaires were developed for diagnose and follow up studies of CTS (26). We preferred simple subjective variables VAS-pain (6,11), severity symptom score (12,13), awakening score (12,13) for evaluations. These are not gold standards to diagnose for CTS (8-10). There were not statistically significant differences between both groups. Pain relief after treatment with a sham is a well-recognized phenomenon that may be due to changes in pain perception mediated circulating opioids (27). Pain is the most important factor, which affect quality of life (28). One of the limitations of our study was that we did not use a questionnaire for quality of life at follow up.

Our intention was to gather homogeneous data as possible. At the baseline study, SDL and VSNC were significantly different than sham group. The study did not include severe CTSs with thenar atrophy because of the trial's homogeneity. In future trials, sample size of groups can be increased.

Electrophysiologic studies are gold standard to diagnose for CTS (9,10,29,30). One of the reasons of greater standard deviations in data are more than one examiner performed the test, but in our study, all examinations were done by the same investigator (9). CTS patients with milder symptoms may show normal standard EMG and nerve conduction studies (29). Standard approach does not account for variation in pretest probability of disease as put forth in Bayes theorem: that is, that the post test probability of a specific abnormal test results declines as pretest probability of disease declines. If pretest probability of disease is low, an abnormal test result using standard cut offs of means \pm SD, for example, may not suffice to confirm median neuropathy at wrist (30). Symptomatic improvement could also be due to change in sympathetic fibers. Standard techniques for measuring nerve conduction velocities give only information on the largest and fastest conducting myelinated nerve fibers; therefore we were not able to detect any change in function of small, unmyelinated nerve fibers. Because of these, there were not statistically significant differences.

Carter conducted a randomized, placebo controlled double-blind study about the effectiveness of magnet therapy in CTS patients' pain and their result consisted with our finding (6). Lawrence et al. showed that magnetic wristbands had protective effect in mild CTS but magnets have no benefit in serious and chronic CTS (23).

On et al. (31) treated CTS patients with very low frequenced (3Hz) PMFT. They reported that very low frequenced PMFT was not superior to placebo. Frequency in our study was 25 Hz. Higher frequencies worked by authors and they suggested that 60 Hz was not harmful, and an effective dose (32). Various frequencies of PMFT for CTS may study in future trials.

Weintraub and Cole studied PMFT's effect to peripheral neuropathy (33). Severe neuropathies more healed with magnetic field in their study, but there was no placebo control.

Raji and Bowden assessed effectiveness of PMFT compared with sham on lesions of the common peroneal nerve in rats and noticed that PMFT accelerated the recovery of injured limbs (34).

Weintraub and Cole studied an interesting study on dynamic and static magnetic fields for CTS. Highly statistic improvements were found (35), but the dose of application time and therapy period is longer than ours.

The effectivenesses of both treatments to electrophysiological endpoints were compared after therapy and one month later, no significant difference was observed. This may related two reasons: 1. the patients took their ergonomic precautions more attentively with placebo effect of the placebo therapy, 2. spontaneous healing was seen in the CTS that had never been treated (especially on the patients who are young and whose symptome period is short) (36,37).

The various results of magnetic fields therapy in literature were found different, because of application dose, time and period of magnetic field were not exact. Controlled, randomised studies are needed for a realistic conclusion.

As a consequence we conclude that magnetic field and placebo magnetic field treatments in the patients with idiopathic carpal tunnel syndrome are effective to both clinical and electrophysiological endpoints in short term but not superior to each other.

References

1. Dawson DM. Entrapment Neuropathies of the upper extremities. *N Engl J Med* 1993;329:2013-8.
2. Werner RA, Andary M. Carpal tunnel syndrome: pathophysiology and clinical neurophysiology. *Clin Neurophysiol* 2002;113:1373-81.
3. Iob I, Battaglia C, Rossetto L, Ermani M. The Carpal Tunnel Syndrome, anatomo clinical correlations. *Neurochirurgia* 2000;46:355-7.
4. Yocum DE. The many faces of carpal tunnel syndrome. *Arch Intern Med* 1998;158:1496.
5. Herbert R, Gerr F, Dropkin J. Clinical evaluation and management of work-related carpal tunnel syndrome. *Am J Ind Med* 2000;37:62-74.
6. Carter R, Aspy CB, Mold J. The effectiveness of magnet therapy for treatment of wrist pain attributed to carpal tunnel syndrome. *J Fam Pract* 2002;51:38-40.
7. Livingston JD. Magnetic therapy: plausible attraction? *Skeptical inquirer* 1998. <http://www.acemagnetics.com/eduarticles-magsportsbracelets-plausibleatt.html>. <http://www.acemagnetics.com/eduarticles-magsportsbracelets-plausibleatt.html>
8. Report of the Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter for carpal tunnel syndrome. *Neurology* 1993;43:2406-9.
9. American Association of Electrodiagnostic Medicine, American Academy of Neurology, American Academy of Physical Medicine and Rehabilitation. Practice parameter for electrodiagnostic studies in carpal tunnel syndrome: Summary statement. *Muscle Nerve* 22: Supplement 8: S141-S143, 1999.
10. Jackson DA, Clifford JC. Electrodiagnosis of mild carpal tunnel syndrome. *Arch Phys Med Rehabil* 1989;70:199-204.
11. Carlsson AM. Assessment of chronic pain: aspects of the reliability and validity of the visual analogue scale. *Pain* 1983;16:87-101.
12. Oztas O, Turan B, Bora I, Karakaya MK. Ultrasound therapy effect in carpal tunnel syndrome. *Arch Phys Med Rehabil* 1998;79:1540-4.
13. Giannini F, Passero S, Cioni R, et al. Electrophysiologic evaluation of local steroid injection in carpal tunnel syndrome. *Arch Phys Med Rehabil* 1991;72:738-42.
14. Ebenbichler GR, Resch KL, Nicolakis P, et al. Ultrasound treatment for treating the carpal tunnel syndrome: randomised sham controlled trial. *BMJ* 1998;316:731-5.
15. Gerritsen AAM, de Vet HCW, Scholten RJPM, Bertelsmann FW, de Krom MCTFM, Bouter LM. Splinting vs surgery in the treatment of carpal tunnel syndrome. *JAMA* 2002;288:1245-51.
16. Tudiver F, Johnson ED, Brown MO. Does surgery for carpal tunnel syndrome improve outcomes? *J Fam Pract* 2003;52:70-2.
17. Michlovitz SL. Is There a Role for Ultrasound and Electrical Stimulation Following Injury to Tendon and Nerve? *J Hand Ther* 2005;18:292-6.
18. Gökoğlu F, Findikoğlu G, Yorgancıoğlu ZR, Okumuş M, Ceceli E, Kocaoğlu S. Evaluation of iontophoresis and local corticosteroid injection in the treatment of carpal tunnel syndrome. *Am J Phys Med Rehabil* 2005;84:92-6.
19. Michlovitz S, Hun L, Erasala GN, Hengehold DA, Weingand KW. Continuous low-level heat wrap therapy is effective for treating wrist pain. *Arch Phys Med Rehabil* 2004;85:1409-16.
20. Rubik B, Becker RO, Flower RG, Hazlewood CF, Liboff AR, Walleczek J. Applications in medicine-Alternative medicine: Expanding medical horizons. Washington DC: US government printing office, 1996;45-65.
21. Markov MS, Colbert AP. Magnetic and electromagnetic field therapy. *J Back Musculoskeletal Rehab* 2001;15:17-29.

22. Frey AH. Differential biologic effects of pulsed and continuous electromagnetic fields and mechanisms of effect. *Ann N Y Acad Sci* 1974;238:273-9.
23. Lawrence R, Rosch PJ, Plowden J. Magnet therapy. The pain cure alternative, Rocklin, CA: Prima Publishing, 1998, 241.
24. Diniz P, Shomura K, Soejima K, Ito G. Effects of pulsed electromagnetic field (PEMF) stimulation on bone-tissue-like formation are dependent on the maturation stages of the osteoblasts. *Bioelectromagnetics* 2002;23:398-405
25. Fanelli C, Coppola S, Barone R, et al. Magnetic fields increase cell survival by inhibiting apoptosis via modulation of Ca²⁺ influx. *FASEB J* 1999;13:95-102.
26. Thomsen JF, Mikkelsen S. Interview data versus questionnaire data in the diagnoses of carpal tunnel syndrome in epidemiologic studies. *Occup Med (Lond)* 2003;53:57-63.
27. Levine JD, Gordon NC, Fields HL. The mechanism of placebo analgesia. *Lancet* 1978;23:654-7.
28. Feuerstein M, Burrell LM, Miller VI, Lincoln A, Huang GD, Berger R. Clinical management of carpal tunnel syndrome: a 12-year review of outcomes. *Am J Ind Med* 1999;35:232-45.
29. Girlanda P, Quartarone A, Sinicropi S, et al. Electrophysiological studies in mild idiopathic carpal tunnel syndrome. *Electroencephalogr Clin Neurophysiol.* 1998;109:44-9.
30. Nodera H, Herrmann DN, Holloway RG, Logigian EL. A Bayesian argument against rigid cut-offs in electrodiagnosis of median neuropathy at the wrist. *Neurology* 2003;60:458-64.
31. On AY, Cumalı A, Kirazlı Y, Celeboğlu G. Karpal tünel sendromunda çok düşük frekanslı manyetik alan tedavisinin etkinliği. XVII. Ulusal fiziksel tıp ve rehabilitasyon kongresi 1999:432.
32. Bailey WH and Nyenhuis JA. Thresholds for 60 Hz Magnetic Field Stimulation of Peripheral Nerves in Human Subjects. *Bioelectromagnetics* 2005;26:462-8.
33. Weintraub MI, Cole SP. Pulsed magnetic field therapy in refractory neuropathic pain secondary to peripheral neuropathy: electrodiagnostic parameters—pilot study. *Neurorehabil Neural Repair* 2004;18:42-6.
34. Raji AR, Bowden RE. Effects of high-peak pulsed electromagnetic fields on the degeneration and regeneration of the common peroneal nerve in rats. *J Bone Joint Surg Br* 1983;65:478-92.
35. Weintraub MI, Cole SP. A Randomized Controlled Trial of the Effects of a Combination of Static and Dynamic Magnetic Fields on Carpal Tunnel Syndrome. *Pain Med* 2008;9:5:493-504.
36. Olney RK. Carpal tunnel syndrome. Complex issues with a simple condition. *Neurology* 2001;56:1431-2.
37. Padua L, Padua R, Aprile I, Pasqualetti P, Tonali P; Italian CTS Study Group. Carpal tunnel syndrome. Multiperspective follow-up of untreated carpal tunnel syndrome. *Neurology* 2001;56:1459-66.