



ORIGINAL ARTICLE

Pulsed magnetic field versus ultrasound in the treatment of postnatal carpal tunnel syndrome: A randomized controlled trial in the women of an Egyptian population



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Abbreviations: CTS, carpal tunnel syndrome; PEMF, pulsed electromagnetic magnetic field; US, ultrasound; MMDL, median motor distal latency; MSDL, median sensory distal latency; VAS, visual analogue scale; EMG, electromyography; MSDL, median segmental sensory distal latency; NCSs, nerve conduction studies; CTSQ, carpal tunnel syndrome questionnaire; MSCV, median sensory conduction velocity; MMCV, median motor conduction velocity; NCV, nerve conduction velocity.

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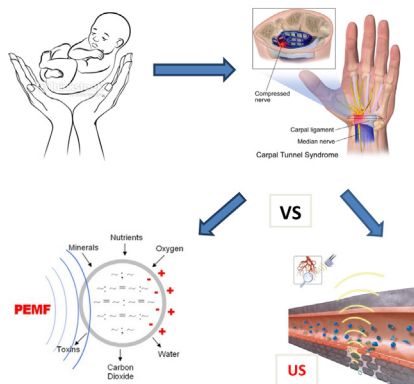
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The aim of this study was to compare the effects of pulsed electromagnetic field versus pulsed ultrasound in treating patients with postnatal carpal tunnel syndrome. The study was a randomized, double-blinded trial. Forty postnatal female patients with idiopathic carpal tunnel syndrome were divided randomly into two equal groups. One group received pulsed electromagnetic field, with nerve and tendon gliding exercises for the wrist, three times per week for four weeks. The other group received pulsed ultrasound and the same wrist exercises. Pain level, sensory and motor distal latencies and conduction velocities of the median nerve, functional status scale and hand grip strength were assessed pre- and post-treatment. There was a significant decrease ($P < 0.05$) in pain level, sensory and motor distal latencies of the median nerve, and significant increase ($P < 0.05$) in sensory and motor conduction velocities of the median nerve and hand grip strength in both groups, with a significant difference between the two groups in favour of pulsed electromagnetic field treatment. However, the functional status scale showed intergroup no significant difference ($P > 0.05$). In conclusion, while the symptoms were alleviated in both groups, pulsed electromagnetic field was more effective than pulsed ultrasound in treating postnatal carpal tunnel syndrome.

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Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy, which results from median nerve compression [1,2]. Prevalence of CTS in the general population is 3.8% when diagnosed clinically and 2.7% when diagnosed neurophysiologically [3]. Women are more susceptible to CTS, with a 70% incidence rate, especially middle-aged women [4]. CTS is a common complaint during pregnancy, as the existing data show the prevalence rate of CTS during pregnancy to be as high as 62% [5,6]. CTS usually develops in the second half of pregnancy because of fluid retention, due to decreased venous circulation, which causes swelling of tissues [7]. Another factor that increases CTS rates during pregnancy is hormonal alterations, including increased oestrogen, aldosterone, and cortisol levels. In addition, increased levels of prolactin are strongly correlated with CTS symptoms worsening during the night, which coincides with the prolactin circadian rhythm [8]. Further, release of relaxin can lead to relaxation of the transverse carpal ligament, leading to its flattening, and subsequent compression of the median nerve [9]. Although most pregnant women experience symptom relief

following delivery, a significant percentage continue to have some level of complaint up to three years after giving birth [10]. The most typical symptoms of CTS are numbness and tingling in the distribution of the median nerve, burning sensation, pain, as well as loss of grip strength and dexterity [11].

There are several therapeutic options for patients with CTS depending on various factors, including the stage of the disease, the severity of the symptoms, and patients' preferences. Non-surgical intervention is recommended as the first-line treatment, in cases of mild to moderate CTS. Surgery is reserved for patients with severe CTS, and those who have experienced failure of conservative treatment. The same treatment strategy is used for postnatal patients with CTS [12].

Non-surgical treatment modalities used for the management of CTS are numerous and include medical and physical therapy. Primary physical therapy interventions are splinting, nerve and tendon gliding exercises, acupuncture, low-level laser, and ultrasound with or without phonophoresis. Electromagnetic therapy is less widely used than these other therapies as currently there is limited research into the effects of electromagnetic therapy on CTS [13].

To our knowledge, no study has yet compared magnetic field therapy (which has limited research supporting its use), and ultrasound (which is among the most common treatments for CTS), in postnatal women, a population with a high incidence of CTS. Thus, our aim was to investigate which modality gives better results in treating CTS.

Subjects and methods

Subjects

The initial sample was pregnant women clinically diagnosed with CTS in their third trimester; they were recruited and screened for eligibility in this study (Fig. 1). After the approval of the Research Ethical Committee P.T.REC/012/001211, of the Faculty of Physical Therapy, Cairo University, and clinical trial

registration in *Clinicaltrial.gov* with identifier number NCT02745652, subjects were selected from the obstetric, orthopaedic and neurological outpatient clinics in *Al Kasr Al Ani Hospitals* and the Faculty of Physical Therapy, Cairo University. Patients were advised to wear a hand splint until giving birth and come back three months after delivery for baseline measures and initiation of treatment.

An informed consent form was signed by each subject prior to starting the study. Participants were randomly assigned into two groups using a random number table, and the selection process was performed by a third party not involved in the research. The study was double-blinded and the participants were randomized into the following two equal groups: group A (n = 20), who received pulsed electromagnetic field (PEMF), and group B (n = 20), who received pulsed ultrasound (US). Both groups received nerve and tendon gliding

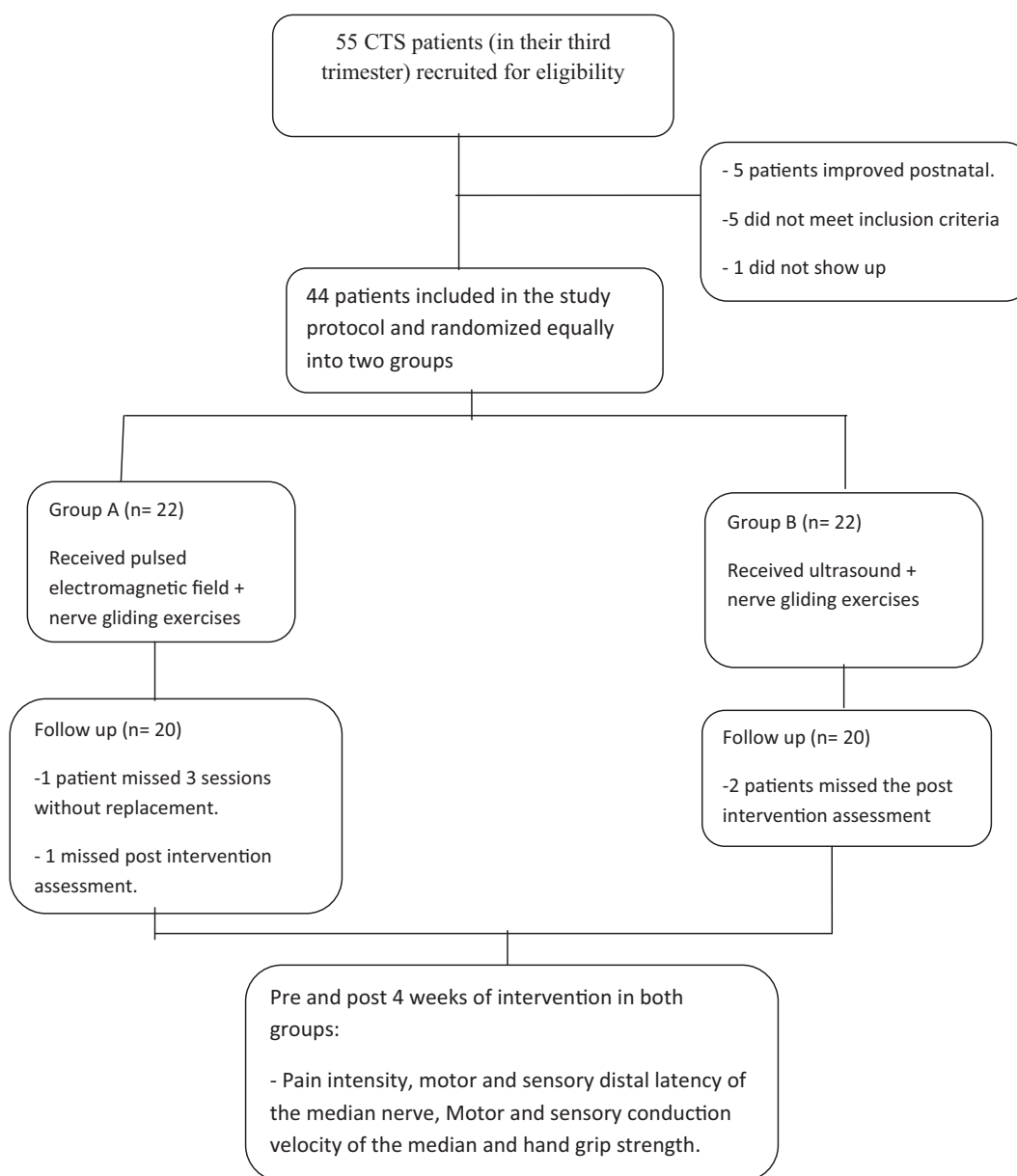


Fig. 1 Flowchart of the patients.

exercises for 5 min. Treatment in both groups was conducted for four weeks, three times per week with a total of 12 treatment sessions. The study started in May 2014 and ended in March 2015.

The following inclusion and exclusion criteria were designed to select a relatively homogeneous group of patients.

Inclusion criteria were unilateral affection, mild to moderate CTS with positive electro-diagnostic findings of prolonged median motor distal latency (MMDL) above 4 ms, and prolonged median sensory distal latency (MSDL) above 3.5 ms [14]. Positive both or either Phalen's and Tinel's tests, both tests have high percentages of sensitivity (73% and 67% respectively), and specificity (40% and 30% respectively), for CTS diagnosis [15]. Lastly, subjects reported pain intensity of more than five on the visual analogue scale (VAS).

Exclusion criteria for the study were electro-neurographic and clinical signs of axonal degeneration of the median nerve [14], and orthopaedic or neurological disorders of the neck or the upper limb such as cervical radiculopathy, pronator teres syndrome or double crush syndrome. Patients with pre-existing CTS before their most recent pregnancy, current pregnancy, diabetic neuropathy and thoracic outlet syndrome were excluded. Further exclusion criteria were wasting of thenar muscles, ulnar neuropathy, rheumatoid arthritis, previous fractured carpal bone, and previous surgery in the forearm, especially transverse ligament release.

Assessment was done before and after four weeks of intervention for both groups using the following.

1. *Visual Analogue Scale (VAS)*. It is considered a valid way of assessing pain, and allows graphic representation and numerical analysis of the collected data.
2. *Computerized Electromyography (EMG)*. Tonnie's neuro-screen plus (version 1.59 Art, No: 780918 Erich Jaeger, Inc. Hoechberg, Germany) with Food and Drug Administration (FDA) registration No. 9615102, was used for assessment of the nerve conduction studies (NCSs). MMDL was recorded through wrist stimulation, and proximal latency through elbow stimulation. Both patient's and room temperature were monitored so as not to affect the recording procedures, and the patient's skin was cleaned with alcohol 70% to decrease its resistance. An active electrode (one-centimetre disc recording, either platinum or disposable) was placed over the belly of the abductor pollicis brevis, half the distance between the metacarpophalangeal joint of the thumb and midpoint of the distal wrist crease, while a reference electrode was placed on the distal phalanx of the thumb. For the wrist, a stimulation electrode (cathode distal) was placed 2 cm proximal to the distal wrist crease between the flexor carpi radialis and the palmaris longus tendons. For the elbow, the stimulating electrode was applied at the elbow crease, just medial to the biceps tendon. A ground electrode was placed between the stimulating and recording electrodes using a Velcro strap. Then median motor conduction velocity (MMCV) was calculated. MSDL measuring points were the active electrode, which is a ring electrode placed on the mid-portion of the proximal phalanx of the index finger (or middle finger), and the reference electrode, which is a ring electrode placed on the mid-portion of the middle phalanx of the index finger, with 2.5 cm distance between the two poles (anode is proximal to cathode). Wrist stimulation was performed at

a distance of 14 cm from the ring electrodes (anti-dromic). Percutaneous stimuli were delivered until a supra-maximal response was obtained. Median sensory conduction velocity (MSCV) was calculated on the basis of the latency and the distance between the stimulating and recording electrode. For motor studies, pulse duration was 0.2 ms, filter settings were 10–10,000 Hz, sweep speed was 2–5 m/s per division, and sensitivity was 1000–5000 μ v per division. For sensory studies, pulse duration was 0.05 ms, filter settings were 20–2000 Hz, sweep speed was 1–2 m/s per division, and sensitivity was 5–10 μ v per division [16].

3. *Hand grip dynamometer*. A hydraulic hand dynamometer ("SH5001" SAEHAN Corporation, Masan, South Korea) was used to detect hand grip strength and for measuring the maximum isometric strength of the hand and forearm muscles in kilograms (kg). It is a simple and commonly used test of general strength level [17]. The average of three trials of the affected hand was recorded.
4. *Functional status scale*. This is a part of the Carpal Tunnel Syndrome Questionnaire (CTSQ) [18]. It asks about eight functional activities such as writing, buttoning of clothes, gripping of a telephone handle. Each functional activity is scaled from one to five, where one means none or never and five means very severe.
5. *Phalen test*. The result of the test is positive if numbness or paresthesia develops in the median nerve distribution after flexion of the wrist for 60 s.
6. *Tinel test*. The test is positive if numbness develops in the median nerve distribution after tapping on the volar aspect of the wrist over the course of the median nerve.

Treatment sessions occurred three times per week for four weeks, as follows.

1. All patients in both groups performed nerve and tendon gliding and median nerve gliding exercises [19]. Tendon gliding exercises were done in five steps (straight, hook, fist, table top and straight fist). Median nerve gliding exercises were performed in six steps (fist, straight, wrist extension, wrist and fingers extension, supination, and gentle stretch of thumb). During these exercises, the neck and the shoulder were in a neutral position, and the elbow was in supination and 90 degrees of flexion. At each step, the patient maintained each position for five seconds, for 10 repetitions at each session. These exercises were performed in each session, three times/week for four weeks.
2. PEFM Group treatment protocol used Pulsed Magnetic Field (automatic PTM Quattro PRO, code # F9020079, ASA S.r.l Company, Arcugnano [VI], Italy). This is an ASA magnetic device for magneto-therapy, which has an appliance, motorized bed, and applicable large solenoids, which can be moved to four different positions according to the treatment area, and an additional small solenoid of 30 cm diameter for hand treatment. Patients in this group received pulsed electromagnetic field therapy at frequency 50 Hz and intensity 80 gauss for 30 min. The patient was in sitting position, while the forearm rested on the bed inside the solenoid in a supination position. Safety was evaluated in the PEFM group by recording adverse effects, both those that lead to cessation of treatment (dropouts), and those that did not.

3. US Group treatment protocol used Therapeutic Ultrasound (**Phyaction** 190 I, Uniphy P.O. Box 558.5600 AN Eindhoven, Netherlands). Pulsed mode US was applied over the volar surface of the forearm (the carpal tunnel area) for 15 min per session with a frequency of 1 MHz and intensity of 1.0 W/cm² [20].

Outcome measures

Outcomes recorded before and after the four-week treatment course were pain intensity, median motor distal latency (MMDL) and median sensor distal latency (MSDL), Median sensory conduction velocity (MSCV), median motor conduction velocity (MMCV), the Tinel's test, Phalen's test, hand grip strength and the functional status scale.

Statistical analysis

All the collected data were tabulated and imported into SPSS version 18 to calculate both descriptive and inferential statistics. Descriptive analysis was performed in terms of mean, standard deviation and percentages. While inferential statistics were in the form of a Paired *t*-test to determine the difference within each group, an unpaired *t*-test was done to determine the difference in pre- and post-treatment between both groups. In addition, nonparametric statistics in the form of the Mann–Whitney test was performed to compare intergroup differences for the Tinel's sign, Phalen's test, VAS and functional status scale while intragroup differences were done by Kolmogorov Smirnov test. Furthermore, the work demographic data were tested by Chi-square test. Statistical significance was established at the conventional ($P < 0.05$) with confidence interval (CI) of 95%.

Results

This study included 55 pregnant women with unilateral idiopathic CTS. Of the 55 patients, five did not fulfil the inclusion criteria and were excluded from the study. The exclusions were due to pre-pregnancy diabetes mellitus (two cases), severe CTS with delayed MMDL equalling 9.5 ms (one case), and another two cases diagnosed with thoracic outlet syndrome. In addition, another five patients experienced greatly alleviated CTS symptoms after giving birth and chose to withdraw from the study. These patients all experienced significant postnatal weight loss with a mean difference of 5.5 kg ($P = 0.0001$). Lastly, one patient did not return at the three-month follow-up. During the study, there were four additional cases lost to follow-up, two cases from each treatment group. Thus, the final sample consisted of 40 patients, 20 in each group. The demographic data for both groups were tested pre-intervention to confirm homogeneity and no significant difference was found ($P > 0.05$) (Table 1).

The comparisons of intragroup mean values of all variables in both groups, before and after end of the treatment showed a significant intragroup improvement in both groups (Table 2). Furthermore, Table 3 summarizes the intragroup differences for the Tinel's test, Phalen's test, VAS, and the functional status scale.

Table 1 Demographic data of subjects in both groups.

	PEMF Group n = 20	US Group n = 20	<i>P</i> value
Age (mean ± SD)	30.75 (2.33)	29.4 (2.41)	0.92
Weight (mean ± SD)	80.63 (8.08)	81.45 (5.48)	0.72
Height (mean ± SD)	170.15 (9.29)	167.65 (5.89)	0.31
Parity (mean ± SD)	2.1 (0.91)	2.0 (0.92)	0.71
Type of work (n, %)			
^a Housewives	9 (45%)	10 (50%)	0.819 ^a
^a Administrative work	11 (55%)	10 (50%)	1.000 ^a

Units for age in years, weight in kg, height in cm and parity in number of times.

^a Chi² test.

Clinical outcomes

Pain (VAS), showed significant improvement at the end of treatment in both groups, PEMF and US groups ($P = 0.0001$ and 0.021), respectively. PEMF leads to a 4.93 point reduction in VAS, while the US group had a 1.3 point reduction with a significant difference in the rate of improvement ($P = 0.0001$) in favour of PEMF (Table 3). Pre-treatment, the Tinel's test was positive in 15 (75%) of the PEMF group and 17 (85%) of the US group and these numbers decreased significantly after treatment to 5 (25%) and 6 (30%) subjects, respectively. There was non-significant difference ($P = 0.727$) between the groups at the end of treatment (Table 3). The same was true for the Phalen's test, as positive results were observed in 13 (65%) and 14 (70%) in both PEMF and US groups, respectively, and were reduced significantly to 4 (20%) and 6 (30%), respectively. There was a non-significant difference ($P = 0.471$) between the groups at the end of treatment (Table 3).

Hand grip strength showed significant improvement in both groups at the end of the intervention periods (Table 2), and PEMF showed a significantly higher level of improvement ($P = 0.017$, CI 0.32–2.68) in comparison with the US group's hand grip strength. The functional status scores showed significant improvement intragroup ($P = 0.0001$) in both groups but there was non-significant difference ($P = 0.414$) between groups (Table 3).

Electrophysiological outcomes

Both MSDL and MMDL were significantly decreased, and MSCV and MMCV were significantly improved, in both groups at the end of the treatment ($P < 0.05$) (Table 2). PEMF showed significant intergroup differences in both MSDL ($P = 0.001$, CI -2.23–(-1.42)) and MSCV ($P = 0.0001$, CI 15.3–20.03), with mean differences of 1.83 and 17.63 respectively, in comparison with the US group. In addition, both MMDL ($P = 0.007$, CI -1.10–(-0.25)) and MMCV ($P = 0.0001$, CI 3.8–7.9) showed significant differences in favour of the PEMF group with mean differences of 0.67 and 5.86, respectively.

Discussion

CTS is a painful, debilitating condition; it has many therapeutic options, but no single treatment modality has been

Table 2 Comparison of mean pre and post treatment in both groups.

	PEMF Group (n = 20)					US Group (n = 20)						
	Pre-ttt	Post-ttt	MD	95% CI		P value	Pre-ttt	Post-ttt	MD	95% CI		P value
				L	U					L	U	
Body weight (kg)	80.63 (8.08)	79.05 (7.26)	1.57	0.14	3.00	0.033	81.45 (5.48)	80.0 (5.09)	1.45	0.71	2.19	0.001
MSDL (msec)	4.53 (0.71)	2.47 (0.83)	2.06	1.67	2.4	0.001	4.41 (0.92)	4.3 (0.89)	0.11	-0.08	0.27	0.002
MSCV (msec)	37.62 (6.44)	59.04 (13.15)	21.42	-23.6	-19.7	0.001	36.01 (5.51)	41.4 (4.2)	5.39	-7.2	-3.51	0.001
MMDL (msec)	4.44 (0.67)	3.96 (0.67)	0.48	0.3	0.7	0.001	4.74 (0.76)	4.63 (0.8)	0.11	0.02	0.23	0.001
MMCV (m/s)	54.21 (5.96)	60.31 (7.31)	6.1	-7.31	-4.88	0.002	53.36 (5.57)	54.45 (5.46)	1.09	-2.13	-0.17	0.001
Hand grip strength (kg)	18.10 (2.4)	21.60 (1.8)	3.5	-4.12	-2.88	0.001	16.75 (2.3)	20.10 (1.8)	3.35	-3.9	-2.79	0.001

Data presented as mean (SD), MD: mean difference, ttt: treatment, CI: confidence interval, L: lower CI, U: upper CI, MSDL: median sensory distal latency, MMDL: median motor distal latency, MSCV: median sensory conduction velocity, MMCV: median motor conduction velocity.

definitively established as superior to any other [21]. The results from conservative treatments vary, and there is no widespread agreement on the best method of treatment. Likewise, the results of surgery, with either an open or endoscopic transverse carpal ligament release, are inconsistent [22].

Forty postnatal women who developed CTS during their third trimester were involved in this study and were divided randomly into one of two treatment protocols: PEMF or therapeutic US. The data showed greater alleviation of disease symptoms with PEMF in comparison with therapeutic US in all outcome measures except for the functional status scale, which showed no significant difference between the two groups.

In the current study, five cases from the initial antenatal sample had their CTS symptoms diminish in the first two weeks after delivery. They all had significant postnatal weight loss ($P = 0.0001$), so their CTS regression was likely strongly related to their weight loss [23]. However, the rest of the women participants still had CTS postnatally, which is consistent with the fact that a significant percentage of women still have CTS symptoms up to three or more years after delivery, and continue to wear splints [10].

Additionally, CTS is associated with hand-intensive activities such as housework and typing, which may contribute to the higher incidence in women [24]. This is consistent with the current study, in which the participants were either housewives or administrative workers, in addition to being caregivers of their new-born child.

The Phalen's and Tinel's tests are clinical tests for CTS; both have high sensitivity and specificity [15]. In the current study, even though not all the enrolled patients had positive results in both these clinical tests, they were still given treatment in both groups. This was because, while not all pregnant women exhibit CTS symptoms, most, if not all, exhibit impaired median nerve function [25]. In fact, these clinical signs were found to be positive in a higher percentage of pregnant women to confirm CTS diagnosis, compared to neurophysiological indicators [26].

Both groups performed nerve and tendon gliding exercises as they are commonly employed for treating symptoms of CTS and are believed to improve axonal transport and nerve conduction [27]. The benefits of these exercises are prevention of adhesion formation even if the wrist is immobilized [28], reduction of pressure in the carpal tunnel, and maximization of the relative excursion of the median nerve and the flexor tendons [29]. These benefits were consistent with what was observed in the current study.

The superior intergroup improvements that were recorded in the PEMF group are attributable to the effects of PEMF on pain perception in the form of neuron firing, calcium ion movement, endorphin levels, acupuncture action, and nerve regeneration [30,31]. A gating response with simultaneous stimulation of the A δ fibres produces an inhibitory antinociceptive effect on C fibres, which is compatible with the Melzack–Wall hypothesis [31].

The PEMF group showed increased median nerve distal latency and nerve conduction velocity (NCV) that can be attributed to the stimulation of endothelial release of fibroblast growth factor beta-2 (FGF-2) [32], which stimulates neurotrophic factors and improves the micro-environment of the tissues, leading to regeneration of the nerve [33]. In the available literature, there is limited research on PEMF treatment

Table 3 Tinel's and Phalen's tests, VAS, and functional status scale in both groups.

		Median	IQR	Significance
Tinel sign	PEMF (n = 20)	0.50	1–0.25	0.0001*
	US (n = 20)	1.00	1–0	0.0001*
	Post intergroups	0.00	1–0	0.727
Phalen test	PEMF (n = 20)	0.00	1–0	0.0001*
	US (n = 20)	0.50	1–0	0.0001*
	Post intergroups	0.00	1–0	0.471
Functional status scale	PEMF (n = 20)	29.00	31–26	0.0001*
	US (n = 20)	28.00	32–25.25	0.0001*
	Post intergroups	26.00	28.75–24	0.414
VAS	PEMF (n = 20)	5.00	7–2	0.0001*
	US (n = 20)	6	7–4.25	0.021*
	Post intergroups	4.00	5–2	0.0001*

IQR = interquartile range.

* Significance $P < 0.05$.

for CTS [13]; nevertheless, a few studies support the current findings. In such studies, pilot data of static [34] and dynamic PEMF [35,36] directed to the carpal tunnel region revealed significantly reduced neuropathic pain. Another research trial applied combined static and dynamic magnetic fields for 4 h per day over two months. There was significant pain reduction, but only mild improvement in objective neuronal functions in the magnetic treatment group versus placebo [37]. This mode of treatment was not appropriate in the current study because of the need to avoid long-term exposure of the newborn to PEMF at home. Despite there being no prior recorded side effects with treatment by magnetic therapy [38], patients were instructed not to bring their babies during sessions. They were also instructed to report side effects at any time, such as dizziness, headache, metallic taste in the mouth, or seizures. Fortunately, no patient in the PEMF group reported any of these side effects.

In contrast to the previously mentioned studies that found significant improvement with PEMF treatment, two small randomized trials [39,40] concluded that there were no differences between the PEMF treatment and placebo groups. Both groups experienced insignificant improvement in symptoms. These results may be due to the treatment short duration (two weeks of PEMF application) in these studies.

Despite the intergroup superior effect of PEMF, the US group also exhibited significant intragroup improvements. These improvements are attributable to the ultrasonic thermal effects, leading to an increase in blood flow, local metabolism and tissue regeneration, and reduced inflammation, oedema and pain, thereby facilitating the recovery of nerve compression [41]. There is an inverse relationship between fibre size and sensitivity to US; hence, C fibres are more sensitive than A fibres. This selective absorption by smaller fibres may lead to a decrease in pain transmission [42]. Furthermore, the current study used deep, pulsed US (1 MHz and intensity of 1.0 W/cm²) over the carpal tunnel for 15 min, since superficial, continuous US was found to be no more effective than placebo US, and did not improve median nerve conduction [43,44].

In addition, deep pulsed US has been shown to decrease pain and paresthesia symptoms, reduce sensory loss, and improve median NCV and strength when compared with placebo US [43,45]. This form of US treatment can also

provide a positive effect on sensation and patient-reported symptoms [43]. In the current study, this was captured by the functional status scale, which showed no significant difference between the two groups.

Conclusions

It can be concluded that PEMF has a significant and superior effect on CTS in postnatal women, as compared to therapeutic US. This superior effect was found in the reduction in pain, improvement in the electrophysiological studies, and hand grip strength. There are no reported side effects, discomforts, or known health risks from PEMF therapy, and it is generally accepted that brief exposure to this modality is safe [38,46]. PEMF has lower treatment costs than surgery [47], but its cost effectiveness in comparison with other therapeutic options needs further investigation. There is a need to develop a treatment guideline for CTS, which includes a combination of different modalities and techniques.

Limitations

The current study had some limitations that should be addressed in future research, such as the small sample size. The literature lacks information about the standard PEMF dose for CTS, so a comparison of different PEMF doses is also needed. In addition, the current study did not investigate the long-term effect of the interventions.

Conflict of interest

The authors have declared no conflict of interest.

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