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Original Article

Acupuncture in treatment of carpal tunnel syndrome: A randomized controlled trial study

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Abstract

BACKGROUND: Carpal tunnel syndrome (CTS) is the most prevalent form of peripheral neuropathy. The efficacy of acupuncture in management of mild to moderate CTS has been investigated in limited studies with controversial results. The aim of this study was to assess the short-term effects of acupuncture in treatment of mild to moderate carpal tunnel syndrome.

METHODS: In a randomized controlled trial study, participants were randomly assigned to either control group which night splinting, vitamin B1, B6 and sham acupuncture for four weeks were administered, or intervention group that underwent acupuncture in 8 sessions over 4 weeks and night splinting. The clinical symptoms using global symptom score (GSS) and electrophysiological parameters were assessed at baseline and four weeks after the intervention.

RESULTS: Of 72 patients met the inclusion criteria, 64 patients actually completed the 4 week intervention and were evaluated for the outcome. There was a statistically significant difference in GSS between two arms of treatment after the intervention ($p < 0.001$) Using repeated measure ANOVA, the GSS in acupuncture group was significantly different after 4 weeks ($p <0.001$). Among electrophysiological parameters, nerve conduction velocity (NCV) was significantly different between two groups after 4 weeks ($p = 0.02$). Other parameters showed no statistically significant difference after intervention ($p > 0.05$).

CONCLUSIONS: Our findings indicated that the acupuncture can improve the overall subjective symptoms of carpal tunnel syndrome and could be adopted in comprehensive care programs of these patients.

KEYWORDS: Carpal Tunnel Syndrome, Acupuncture, Global Symptom Score, Electrophysiological Parameters.

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Carpal tunnel syndrome (CTS) is the most prevalent form of peripheral entrapment syndrome, characterized by numbness, tingling, hand pain, and muscular dysfunction.[1] The incidence of this disorder is 1-3 cases per 1000 subjects per year in United States and can occur in all ages[2] with more incidence in women.[3]

Several interventions both conservative and surgical treatments are proposed for treatment of CTS.[4] According to the recommendations of American Association of Orthopedic Surgeons (AAOS), conservative treatments include splinting, local steroid injection, ultrasound, and oral steroids that are effective in patients with mild to moderate symptoms. Surgery is suggested if conservative treatments fail.[5]

Among several interventions for pain management, acupuncture has received special attention. Acupuncture is the most familiar complementary and alternative medicine, especially in Chinese medical treatments.[6] The

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efficacy of acupuncture in management of mild to moderate CTS has been investigated in limited studies.[7-9]

A recent randomized controlled trial study compared the efficacy of acupuncture with night splinting for CTS and found that electroacupuncture was as effective as night splinting in management of symptoms in mild to moderate CTS.[10] Yang et al. showed that short-term acupuncture treatment is as effective as oral prednisolone in mild to moderate CTS.[11] But recalculation of the mean difference by a systematic review showed no statistical difference ($p = 0.15$), except for distal motor latency in terms of NCS.[12]

In 2010, one systematic review assessed the effectiveness of acupuncture in CTS treatment and found that the existing evidence is not convincing enough to suggest that acupuncture is an effective therapy for CTS.[12] However, National Institute of Health (NIH) confirmed acupuncture for management of mild to moderate CTS,[13] but there is still controversy in its effectiveness.[14,15] The aim of this study was to assess the short term effects of acupuncture in treatment of mild to moderate CTS.

Methods

This was a randomized controlled trial study undertaken in physical and rehabilitative medicine outpatient clinics in Alzahra and Kashani Hospitals, Isfahan, Iran. Diagnosis of patients was made based on at least one of the following clinical criteria which were confirmed by Tinel's and Phalen's tests:[3] 1) Numbness and tingling in the thumb, index finger, middle finger and ring finger (the region innervated by median nerve); 2) Provocation of symptoms by repetitive actions of the hand or wrist; 3) Mitigation of symptoms by changing hand posture or shaking the wrist; 4) Nocturnal symptoms. The diagnosis of all patients with clinically diagnosed CTS, was confirmed by the presence of 1 or more of the following standard electrophysiological criteria:[2] 1) prolonged distal motor latency (DML ≥ 4.2 ms); 2) Prolonged antidromic distal sensory latency (DSL) to the second digit (≥3.6 ms); 3) Reduced wrist-palm sensory nerve conduction velocity (W-P SNCV < 40 ms).

In this study, mild CTS was attributed to the patients with decreased conduction velocity over the palm-wrist segment and delayed DSL, with or without normal median sensory nerve action potential (SNAP) amplitude. Moderate CTS was attributed to patients with abnormally delayed DML and DSL with either decreased median SNAP amplitude.[16]

Exclusion criteria were as follows: Severe CTS; presence of either fibrillation potentials or reinnervation on needle electromyography (EMG) in the abductor pollicis brevis (APB); experiencing symptoms less than 3 months before the study or symptoms improving during the one month initial observation period (to exclude patients who might have spontaneous resolution of symptoms); clinical and electrodiagnostic criteria of associated conditions that could mimic CTS or interfere with its evaluation, such as cervical radiculopathy, proximal median neuropathy, or significant polyneuropathy; evidence of predisposing conditions such as pregnancy, diabetes mellitus, rheumatoid arthritis, hypothyroidism and trauma; previous unfavorable experience of acupuncture or bleeding history; cognitive disorders and unwillingness to participate in the present study.

Between June 2010 and February 2011, participants were randomly assigned using computerized random numbers to control or treatment groups. Night splinting, vitamin B1, B6 and sham acupuncture was administered in control group for four weeks. For sham acupuncture, participants received a non-skin penetrating pricking sensation using a previously validated sham procedure.[17] The needles inserted at similar body locations as the true acupuncture group and the length of time was similar for needle insertion. Intervention group underwent acupuncture in 8 sessions over 4 weeks and also night splinting. Acupuncture consisted of 8 sessions that were 60 minutes each in duration, administrated over 4 weeks (2 sessions per week). Acupuncture was done with 0.25*40 mm size gauge in fixed and classic acupuncture points (PC-7 [Daling], PC-6 [Nei-

guan]) for each patient. All participants were blindfolded during each treatment to prevent patient knowledge of treatment assignment and true and sham acupuncture were done by an expert acupuncturist.

The clinical symptoms were assessed using Global Symptom Score (GSS) at baseline and after 2 and 4 weeks of intervention. This scoring system rates clinical symptoms from 0 (no symptoms) to 10 (very severe symptoms) in the following 5 areas: Pain, numbness, tingling, weakness/clumsiness, and nocturnal awakening. Therefore, the maximum score was 50 that indicated most severe symptoms and the minimum score was 0 that showed absence of symptoms.[18,19]

Electrophysiological parameters were assessed as the secondary outcome at baseline and four weeks after the intervention. These parameters included DML (distal motor latency), sensory NCV (nerve conduction velocity) and DSL (distal sensory latency). All tests were done using an Advantage EMG machine (Medelec synergy, UK). Nerve conduction studies were performed by an experienced electromyographer who was blinded to random assignment. Surface stimulation in sensory and motor nerve conduction studies was done using standard methodology.[16] The electromyographer monitored the hand temperature using an adhesive surface thermistor on the thenar eminence to ensure the hand temperature between 32°C and 34°C.

During the sensory nerve conduction studies, the median sensory nerve fibers were stimulated antidromically with 0.05 ms square pulse at mid-palm and wrist with a distance of 7 cm and 14 cm from the recording ring electrode looped around the proximal interphalangeal joint of the third digit. The reference ring electrode was placed around the distal interphalangeal joint. During the motor nerve conduction studies, the median motor nerve fibers were stimulated with 0.05 ms square pulse at the wrist at a distance of 8 cm proximal to the recording electrode placed over the motor point of the thenar muscles. The reference electrode was placed over the dorsal aspect of the first metacarpophalangeal joint.

This trial was registered in the Iranian Randomized Controlled Trial Registry with number IRCT201108174242N2.The design of the study was approved in Ethics Committee of Vice Chancellor for Research, Isfahan University of Medical Sciences (project no 389393). All participants received trial information and provided written informed consent. In addition, the confidentiality of all information was carefully managed by researchers.

Statistical Analysis

The characteristics of subjects were presented as mean ± SD for the continuous variables and percentage for attributes measured on an ordinal or nominal scale. The independent sample t-test was used to compare the clinical characteristics (nerve conduction and global symptom score) between the two groups at baseline and after the intervention. Repeated measures analysis of variance (ANOVA) was performed to compare GSS between groups at baseline, 2 and 4 weeks after the intervention. The comparison of electrophysiological parameters in the two groups was done via paired-sample t-test. All tests of hypotheses were 2-tailed and the level of significance was set at 0.05. All statistical analyses were performed using SPSS Version 19.0 for Windows.

Results

In general, 72 patients fulfilled the inclusion criteria and were enrolled in the study. Eight patients were excluded due to severe CTS (n=3) and evidence of predisposing conditions including diabetes (n= 2) and pregnancy (n=3). Sixty four subjects (32 patients in the acupuncture and 32 patients in the control group) actually completed the 4 week intervention and were evaluated for the outcome (64 limbs) (Figure 1).

The mean age of patients in acupuncture group was 41.7 ± 9.3 years with a range of 25 to 65 years, of whom 23 patients were female (71.9%). The control group consisted of 25 females (78.1%).The mean age of these patients was 41.1 ± 9.6 years with a range of 25 to 65 years. There was no statistically significant

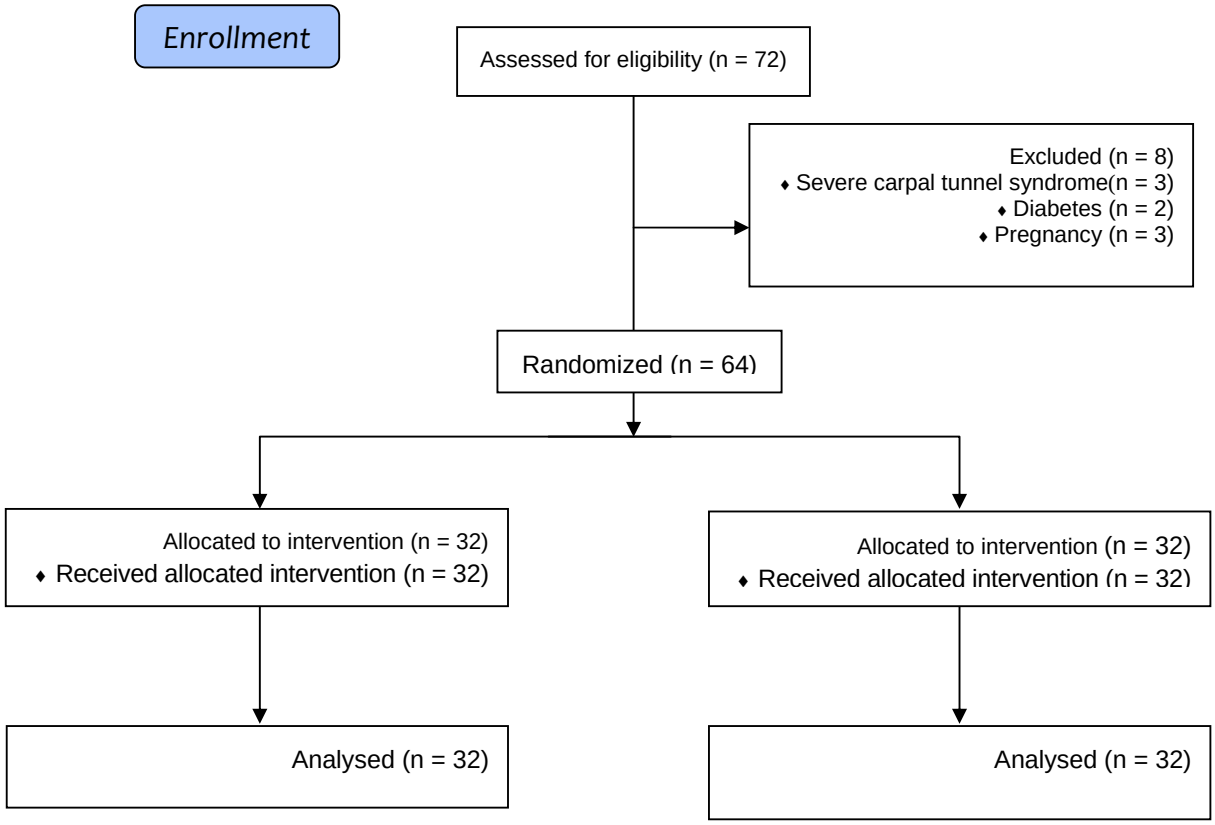

Figure 1. Study profile

difference in demographic data between the two groups at the start of trial ($p > 0.05$) indicating the success of randomization. The mean GSS at baseline was 24.1 ± 8.1 in intervention group and 23.7 ± 8.9 in control group. Baseline characteristics were balanced across treatment arms, indicating the success of randomization ($p = 0.85$).

Using repeated measure ANOVA, the GSS in acupuncture group was significantly different after 4 weeks ($p < 0.001$), whereas the control group remained at about the same level even after 4 weeks ($p = 0.17$). At the end of study, the mean of GSS in acupuncture group showed a progressive loss of clinical effects in comparison to control group ($p < 0.001$).

Among electrophysiological parameters, NCV showed statistically significant difference between two groups after 4 weeks ($p = 0.02$) and the acupuncture group had a significantly better improvement in NCV score ($p=0.02$). The mean of DML and DSL scores were not significantly different at baseline and even after 4 weeks between two arms of treatment ($p > 0.05$). Paired t-test showed similar results before and after the study in each group ($p > 0.05$). The results of GSS and electro physiologic parameters are summarized in table 1.

Discussion

The aim of this study was to assess the short term effects of acupuncture in treatment of mild to moderate carpal tunnel syndrome. Our results showed that patients received acupuncture had significantly better improvement in clinical symptoms of CTS. Among electro physiologic characteristics, NCV showed improvement in the acupuncture group in comparison to the control group.

Acupuncture treatment had superior efficacy when compared to night splinting plus sham acupuncture at least in subjective symp-

Table 1. The mean of Global Symptom Score and electrophysiological parameters in two groups before and after the intervention

Global Symptom Score	Acupuncture Group		Control group		P-value
	Mean	SD	Mean	SD	
Before intervention	24.1	8.1	23.7	8.9	0.85
two weeks after intervention	19.6	8.5	23.1	8.5	0.04
Four weeks after intervention	14.6	5.4	22.5	8.9	< 0.001
P-Value	< 0.001		0.17		
Distal motor latency					
Before intervention	4.2	0.71	4.1	0.43	0.71
Four weeks after intervention	4.1	0.70	4.2	0.42	0.55
P-Value	0.14		0.11		
Distal sensory latency					
Before intervention	4.2	0.59	4.3	0.54	0.32
Four weeks after intervention	4.1	0.74	4.4	0.56	0.07
P-Value	0.19		0.17		
Nerve conduction velocity					
Before intervention	35.1	5.3	33.6	5.8	0.3
Four weeks after intervention	37.6	8.3	33.2	5.9	0.02
P-Value	0.02		0.38		

tom assessment. This result was confirmed objectively by NCV evaluation. However, acupuncture was as effective as night splinting plus sham acupuncture in respect to other electro physiologic parameters. The result of this study was in line with previous research.

A recent randomized trial study with long-term follow-up (13 months) compared acupuncture versus oral steroids in management of CTS. Both groups showed more than 50% improvement in GSS at month 7 and 13. Furthermore, patients with acupuncture treatment had significantly better improvement in GSS and DML and DSL, compared to the steroid group. The results of this study showed greater efficacy of acupuncture both in symptom assessment and objective changes in nerve conduction.[20]

Another randomized controlled trial study compared efficacy of acupuncture with night splinting (5 weeks) for CTS and found that electro-acupuncture was as effective as night splinting in management of symptoms in mild to moderate CTS.[10] Furthermore, a Chinese study showed a promising effect of needle acupuncture compared with steroid block therapy in terms of responder rate.[21] A meta-analysis of acupuncture versus steroid nerve blocks confirmed this result.[12]

On the other hand, some evidence did not demonstrate benefit in symptom relief in acupuncture intervention when compared to placebo or control. Weinstein et al. evaluated the effect of manual acupuncture in comparison with sham acupuncture and found no statistical difference between the real and sham groups.[22] Another randomized controlled trial study found no significant differences between laser acupuncture and placebo on night pain at 3 weeks of follow-up.[23] A Cochrane meta-analysis reviewed twenty one trials of different conservative managements of CTS including one laser acupuncture trial study, concluded that acupuncture do not produce significant benefit.[15] Ineffectiveness of laser acupuncture in CTS was indicated in another systematic re-

view.[19] Both of these reviews indicated that there are limited evidence in this field.

Some studies examined the mechanism of acupuncture on CTS. Studies by functional magnetic resonance imaging (fMRI) showed that acupuncture stimulation caused a change in brain processing or a coordinated limbic response.[24-26] Other studies suggested that acupuncture has an anti-inflammatory and immune modulator effect.[27-29] Although the exact mechanism of acupuncture effects on CTS is not accurately understood, current study demonstrated effectiveness of this method in management of CTS. Two studies investigated side effects of acupuncture in CTS, indicating some side effects such as swelling and pain in right hand.[30] In our study we did not detect any side effect in acupuncture or control group.

Our study, while having much strength, involved some limitations that should be considered. This study was limited due to considering short-term effects, small number of patients in each arm of treatment and more physician visits in the acupuncture group. The small sample size prevented from subgroups analyses to further elaborate the effects of acupuncture in mild and moderate CTS. Further research is recommended to determine long-term outcome and comparison of acupuncture to other conservative managements of CTS.

In conclusion, the results of this randomized controlled trial indicated that acupuncture can improve the overall subjective symptoms of carpal tunnel syndrome and could be adopted in comprehensive care programs of these patients.

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Conflict of Interests
Authors have no conflict of interests.

Authors' Contributions
SK was the main investigator, analyzed the data and wrote the paper. AM contributed to the study design and writing the manuscript. SH helped in designing the study, contributed to the analysis and helped in writing the final manuscript. All authors read and approved the final version of manuscript.

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