



Original Article

Acupuncture plus night splint for quality of life and disability in patients with carpal tunnel syndrome: a randomized controlled trial

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ABSTRACT

Background: Carpal tunnel syndrome (CTS) is a common condition caused by pressure on a nerve in the wrist. This study aimed to evaluate the effects of acupuncture plus night splinting on quality of life, function and pain in patients with CTS.

Methods: This research is a prospective randomized, single-center trial. Acupuncture and night splinting was applied two times a week for five weeks, while the control group received night splinting only. Outcomes measured were Quality of life (Nottingham Health Profile, NHP), function (Boston Carpal Tunnel Questionnaire) and pain (visual analogue scale, VAS).

Results: At the end of the treatment, the acupuncture plus splinting group showed more reduction in the pain level than the splinting group ($p = 0.007$). The change in the pain subscale of the NHP was significantly reduced in the acupuncture plus night splinting group than the night splinting group ($p = 0.001$). The change in sleep and physical activity subscale of the NHP score failed to show significant differences between the two groups. The functional scores also failed to show significant differences between the two groups.

Conclusion: The effect of acupuncture plus night splinting may show significant reduction on pain but failed to show significant differences on the other outcomes compared to the night splinting group. Further studies with larger sample size may confirm the findings.

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1. Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy of the median nerve at the wrist, within the carpal tunnel.¹ It is more frequently observed in the age range of 40–74 years, and the prevalence in the general population is approximately 2.7%.² Women are expected to be at greater risk than men.³ The main cause of CTS is the overuse of hands and wrists, but systemic disorders such as diabetes mellitus, rheumatoid arthritis, hypothyroidism, and pregnancy may also cause median nerve compression.⁴ Major symptoms of CTS to include pain, numbness, and tingling affecting the first three fingers of the hand. Weakness and atrophy of the muscles innervated by the median may occur in some cases.⁵ The diagnosis of CTS generally depends on clinical findings and electrophysiological studies. Treatment choices include rest, non-steroidal anti-inflammatory drugs, physical therapy, conservative techniques (splinting, acupuncture and others) and invasive procedures such as local injections and decompression

surgery.⁶ Although many studies have been carried out on the effect of acupuncture on CTS, its efficacy has not yet been established, even in the latest meta-analyses, and there is no consensus in the literature.^{7,8} Even though the results are controversial, acupuncture has become an increasingly popular method for treating CTS in recent years.^{9,10}

The aim of the present study is to evaluate the effectiveness of acupuncture on pain and its effects on QoL life for patients, as well as to compare the effectiveness of acupuncture combined with night splinting and night splinting alone for patients with CTS.

2. Methods

2.1. Trial design

This study has been designed as a prospective randomized, single-center trial over 5 weeks that compared the effects of acupuncture plus night splinting on clinical outcomes with night splinting in patients with idiopathic primary CTS. This trial was conducted at Ministry of Health Ankara Diskapi Yildirim Beyazit Training and Research Hospital in Turkey from August 2017, and follow-up was completed in January 2019.

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E-mail address: nihal.tezel@saglik.gov.tr (N. Tezel).

2.2. Participants

2.2.1. Inclusion criteria

The patients with idiopathic CTS who applied to the physical therapy and rehabilitation outpatient clinic were included in the study. Study details were explained until the patients completely understood the risks and benefits, and we received written informed consent from the patients who were diagnosed with mild or moderate CTS electrophysiologically.

2.2.2. Exclusion criteria

We excluded patients with secondary CTS owing to polyneuropathy, inflammatory arthropathy, pregnancy, diabetes mellitus, hypothyroidism, malignancy, rheumatoid arthritis, alcoholism, infections, cervical disc pathology, trauma, surgery and contraindication for needlings, such as bleeding tendency or local infection.

2.3. Intervention

Patients who were electrophysiologically diagnosed with CTS were randomized into two groups, acupuncture plus night splinting or night splinting only. Patients in the experimental group received acupuncture two days a week and prefabricated volar neutral wrist splints for five weeks. Patients in the control group used only neutral volar wrist splints at night during treatment. In both groups, patients were asked to wear the splints (0–5 degrees of the wrist extension) for five weeks, only at night. Patients were told not to take any medication other than paracetamol.

Manual acupuncture was treated on all patients for 10 sessions over five weeks, twice a week, by a acupuncture certified physician. Acupuncture points were selected based on acupuncture literature.¹¹ The acupoints that used were as follows: PC7 (Daling), PC4 (Ximen), PC6 (Neiguan), HT7 (Shengmen), Lu9 (Taiyuan), LI11 (Quchi). In this method, thin sterile needles (0.25 × 40 mm size gauge) with high flexibility and safety were used. Thus, six needles were used for six acupoints on the involved side. Patients with bilateral CTS were treated bilaterally. The treatment procedure was performed while the patients lay relaxed on the examination table in the supine position. Needles were inserted vertically into specific points and kept in the points for 20 min. The application was performed according to the Standards for Reporting Interventions in Clinical Trials of Acupuncture.¹² For the control group, night splinting was recommended to patients for five weeks. Both groups were advised to avoid overuse of their hands.

2.4. Outcomes

2.4.1. Primary outcomes

Baseline demographic data were obtained from all patients. The following instruments were completed before (baseline) and after the interventions (5 weeks).

Primary outcome measures were function with Boston Carpal Tunnel Questionnaire (BCTQ), and QoL with the Nottingham Health Profile (NHP).

The BCTQ evaluates functional status score (BCQT FUNCT) and symptom severity score (BCQT SYMPT). BCQT FUNCT evaluates daily life activities with eight questions from “no strain” to “impossible” between 8 and 40 points; higher points are associated with worse hand functions. BCQT SYMPT evaluates symptom severity with 11 questions from “no symptom” to “very severe” between 11 and 55 points; higher points are associated with more severe symptoms.

QoL of the patients was evaluated using the Nottingham Health Profile (NHP). NHP measures health-related QoL within the subgroups of energy, sleep, emotions, pain, mobility and social

isolation, which is scored from 0 to 100 points; higher points are associated with a worse QoL.

2.4.2. Secondary outcomes

Secondary outcome measures were extracted from electrodiagnostic study findings which included median nerve motor distal latency (DML), motor nerve conduction velocity (NCV), sensorial conduction velocity (SCV), sensory DL and palm-wrist sensory NCV measurements were measured according to Oh protocol.¹³ Patients who have peak SCV of the median nerve recorded from the second finger of <41.25 m/s, and who have DML recorded from the abductor pollicis brevis (APB) muscle with the stimulation of median nerve 5 cm proximal to the elbow of >3.6 ms were diagnosed as CTS. The physician made the clinical diagnosis and then directed patients to an electrophysiological test laboratory. Electrophysiological evaluations were performed at baseline and at the end of the treatment. Using standard techniques, all of the electrodiagnostic tests were performed by the same physician (E.K.U) using a Medelec Sapphire 4 ME (Medelec, Old Woking, UK) electromyography (EMG) apparatus.

Pain severity was evaluated using a visual analogue scale (VAS), ranging from 0 (no pain) to 100 mm (worst pain).

Adverse events related to electroacupuncture plus night splinting and only night splinting were recorded.

All patients were evaluated at baseline and after the treatment (5 weeks) by the same clinician blinded to the intervention (E.K.U).

2.5. Sample size

G Power analysis was performed for 10% improvement in pain with effect size $d = 0.667$, power 0.080 and a significance level of 5%. The sample size was estimated at least 20 patients for each group.

2.6. Randomisation

Fifty-one patients (one hundred hands) with carpal tunnel syndromes were randomly allocated to either the experimental group ($n = 26$ patients, 50 hands) or the control group ($n = 25$ patients, 50 hands). We used computer-generated random numbers for simple randomization. But seven patients had not completed follow-up and were excluded from the analysis as well as per-protocol analysis was applied. Forty-four of the patients completed the study. 24 patients (47 hands) in the experimental group and 20 patients (40 hands) in the control group. The flow chart of the study design has been shown in Fig. 1.

2.7. Blinding

The data were collected by an assessor who was blinded to the group allocation.

2.8. Statistical analysis

Statistical Package for the Social Sciences (SPSS 22.0 for Windows) software package was used in the analysis of the data. The continuous variables were evaluated using the Shapiro-Wilk test to determine whether or not they exhibited a normal distribution. In descriptive statistics, the data were expressed as mean ± standard deviation for continuous variables, and as frequencies and percentages (%) for nominal variables using the chi-square test. Statistically significant differences in repeated measurements within the groups were evaluated with the Wilcoxon Signed Rank test. The Bonferroni correction was used to control possible Type I errors in intra-group comparisons ($p < 0.025$). Statistically significant differences

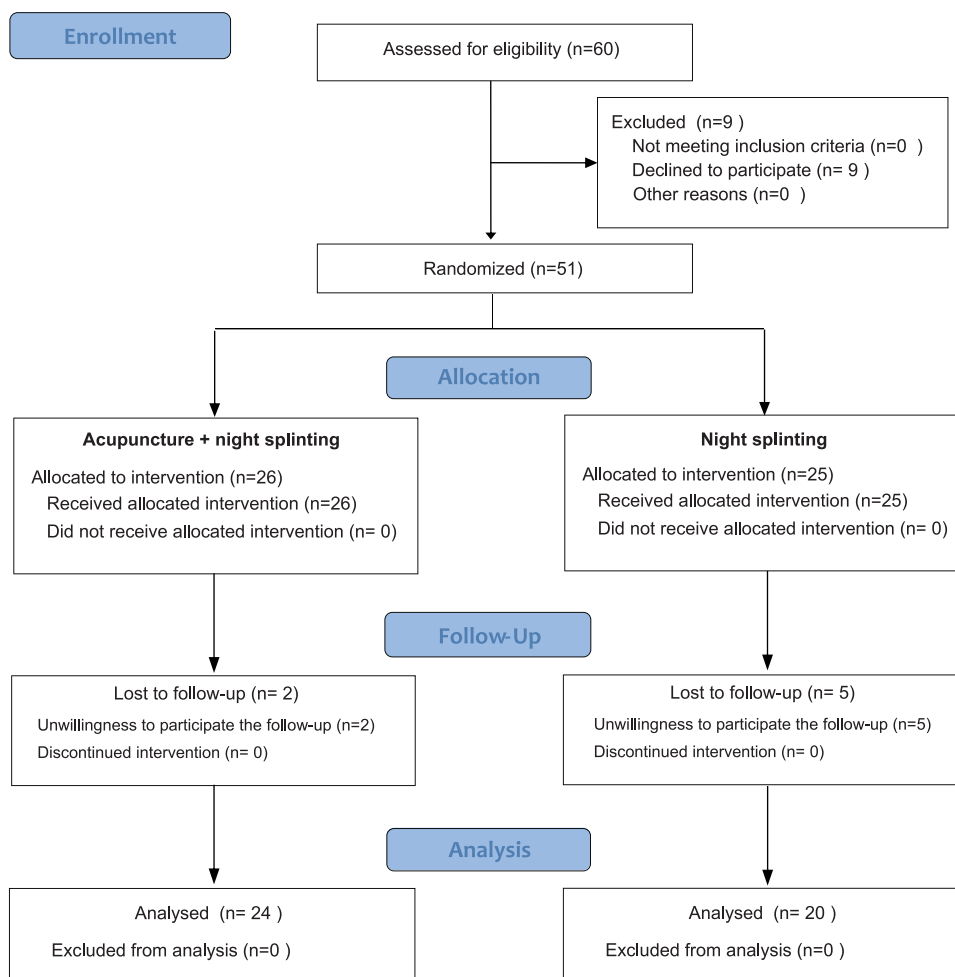


Fig. 1. The flow chart of the study.

between the groups were analyzed with the Mann-Whitney *U* test. Values of $p < 0.05$ were considered statistically significant.

3. Results

There were no significant differences in age, sex, education level, hand dominance, BMI, and baseline clinical measurements between the groups ($p < 0.05$). The demographic and baseline clinical characteristics of the groups are shown in Table 1.

Table 2 shows the results of outcome measures. At the end of the treatment, the acupuncture plus night splinting group showed significant reduction in pain on VAS than the night splinting group ($p = 0.007$) (Table 2). The change in pain subscale of the NHP score were significantly lower in the experimental group at the end of the treatment was significantly better than that for the control group ($p = 0.001$).

At the end of the treatment, there were no significant differences in the change in sleep and physical activity subscale of the NHP score between two groups ($p = 0.862$, $p = 0.818$ respectively).

There were also no significant difference was found in electro-physiological parameters after treatment between two groups.

3.1. Adverse events

There were no serious adverse events related to acupuncture treatment in the included trials. Only two patients reported

redness at the application area in the acupuncture plus night splinting group.

4. Discussion

In our study, we found acupuncture plus night splinting reduces pain level compared to night splinting only. The effects of acupuncture on pain can be explained by many mechanisms. It stimulates local inflammatory and immune responses, such as the release of adenosine and the increase of opioid peptides.¹⁴ These systemic effects are related to a decrease in pain and an increase in functionality and QoL. Previous studies reported the efficacy of electroacupuncture on pain reduction in patients with CTS.^{2,15}

Most studies evaluating the QoL of patients focus after surgery.¹⁶ Our results showed that the acupuncture plus night splinting group showed more improvement in the QoL subscales (i.e., pain, sleep, and physical activity scores) than the night splinting group without statistical differences between two groups.

Patients with CTS usually have sleep-disturbing symptoms, such as waking up due to pain or tingling and numbness at night. The positive effects of acupuncture on sleep have been shown in many publications.¹⁷ The positive effects of acupuncture on sleep may influence positively on the night pain, numbness, and daytime work performance of patients. Yang et al.¹⁸ showed better night awakening in the acupuncture group, which is similar to the finding of our study.

Table 1
Demographic characteristics and baseline values of clinical outcomes.

	Acupuncture plus night splinting (N=24) N (%)	Night splinting (N=20) N (%)	χ^2 or P
Gender			0.90
Female	23 (95.8)	19 (95)	
Male	1 (4.2)	1 (5)	
Hand dominancy			1.00
Right	24 (100)	20 (100)	
Education			0.72
Literate	1 (4.2)	1 (5.0)	
Under 5-year	20 (83.3)	17 (85.0)	
5-year	1(4.2)	1 (5.0)	
8-year	2 (8.3)	1 (5.0)	
Symptom severity (Day)			0.17
Absent	24 (51.1)	22 (55.0)	
Mild	6 (12.8)	11 (27.5)	
Intermediate	16 (34.0)	6 (15.0)	
Severe	1 (2.1)	1 (2.5)	
Symptom severity (Night)			0.71
Absent	4 (8.5)	2 (5.0)	
Mild	22 (46.8)	27 (67.5)	
Intermediate	18 (38.3)	9 (22.5)	
Severe	3 (6.4)	2 (5.0)	
Clinical stage (1–5)			0.86
Stage 1	1 (2.1)	1 (5.0)	
Stage 2	38 (80.9)	35 (75.0)	
Stage 3	8 (17.0)	4 (20.0)	
	Mean \pm SD	Mean \pm SD	
Age (years)	47.1 \pm 7.7	46.6 \pm 8.1	0.83
BMI (kg/m ²)	31.5 \pm 3.6	31.7 \pm 3.4	0.88
VAS (0–10)	7.4 \pm 0.8	7.6 \pm 0.7	0.41
BCTQ			
SYMPT (11–55)	29.8 \pm 5.9	28.8 \pm 5.4	0.58
FUNCT (8–40)	26.8 \pm 9.0	25.8 \pm 8.7	0.72
NHP (0–100)			
Pain	81.2 \pm 18.4	83.8 \pm 13.0	0.95
Energy	63.5 \pm 27.7	61.3 \pm 27.1	0.79
Sleep	36.7 \pm 27.0	38.0 \pm 27.7	0.87
Emotional stress	28.0 \pm 25.1	32.5 \pm 25.1	0.56
Social isolation	8.0 \pm 17.2	12.0 \pm 23.4	0.25
Physical activity	35.0 \pm 24.9	35.2 \pm 26.1	0.99
Electrophysiology			
SCV (m/sec)	33.1 \pm 5.3	33.4 \pm 5.5	0.80
DML (msec)	3.8 \pm 0.7	3.6 \pm 0.6	0.35
Motor amplitude (mV)	9.3 \pm 3.8	9.2 \pm 3.6	0.91
MCV (m/sec)	56.2 \pm 6.0	56.7 \pm 6.3	0.72

BCTQ SYMPT: Boston Carpal Tunnel Questionnaire Symptom severity Score BCTQ FUNCT: Boston Carpal Tunnel Questionnaire Functional Status Score, BMI: body mass index, DML: distal motor latency, MCV: motor conduction velocity, NHP: Notthingam Health Profile, SCV: sensory conduction velocity, SD: standard deviation, VAS: visual analogue scale.

Although acupuncture is shown to improve electrodiagnostic parameters,¹⁹ the underlying mechanism in this improvement has not yet been identified.²⁰ We measured electrophysiological recovery in the EMG parameters of the patients, but the results failed to show the significant differences between groups. The absence of electrophysiological changes may be related to the shortness of the follow-up period.

The main limitation of this study is the generalizability of the results because of small sample size and short treatment session. Furthermore, this study also lacks of using placebo control for investigating specific effects of acupuncture or using active control to find comparative effectiveness.

In conclusion, our results showed that acupuncture plus night splinting may reduce pain level in patients with CTS compared to night splinting. Further studies with large sample size

Table 2
Effects of acupuncture plus night splinting on outcome measures after 5 weeks treatments.

	Acupuncture plus night splinting (N=24)	Night splinting (N=20)	P
BCTQ			
SYMPT (11–55)	23.4 \pm 7.5	22.1 \pm 6.5	0.54
FUNCT (8–40)	20.7 \pm 6.9	19.4 \pm 6.4	0.51
Pain (VAS, 0–10)	4.8 \pm 0.8	5.8 \pm 0.8	0.007
NHP (0–100)			
Pain	42.4 \pm 28.2	56.4 \pm 26.5	0.001
Energy	42.4 \pm 28.2	39.7 \pm 29.6	0.76
Sleep	25.0 \pm 18.7	26.0 \pm 19.3	0.86
Emotional stress	20.2 \pm 26.2	24.6 \pm 27.0	0.61
Social isolation	6.5 \pm 17.2	7.4 \pm 18.3	0.86
Physical activity	22.2 \pm 16.6	21.0 \pm 17.1	0.82
Electrophysiology			
SCV (m/sec)	31.9 \pm 5.1	31.9 \pm 5.4	1.00
DML (msec)	3.8 \pm 0.9	3.8 \pm 0.9	0.69
Motor amplitude (mV)	9.6 \pm 3.8	9.5 \pm 3.6	0.96
MCV (m/sec)	54.6 \pm 10.8	54.8 \pm 11.7	0.94

Values are expressed as mean \pm standard deviation. BCTQ SYMPT: Boston Carpal Tunnel Questionnaire Symptom severity Score, BCTQ FUNCT: Boston Carpal Tunnel Questionnaire Functional Status Score, DML: distal motor latency, Hi-ob scale: Historical Objective Scale, MCV: motor conduction velocity, NHP: Notthingam Health Profile, SCV: sensory conduction velocity, VAS: visual analogue scale.

and appropriate dose of acupuncture are needed to confirm the results.

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Conflict of interest

There are no conflicts of interest to declare.

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Ethical statement

The study was approved by the local ethical committee (approve date 24.07.2017 and number: 40/09) and performed according to Helsinki declaration criteria; signed informed consent forms were collected from all subjects.

Data availability

Data will be made available upon request.

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