Efficacy of Acupuncture versus Night Splinting for Carpal Tunnel Syndrome: A Randomized Clinical Trial

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Objective: *To compare the efficacy of acupuncture with night splinting for carpal tunnel syndrome (CTS).*
Material and Method: *Sixty one mild-to-moderate degree CTS patients, aged 27-67 were randomly assigned to acupuncture (Acu) and night splinting (NS) groups. The Acu group received 10 sessions of electro-acupuncture twice a week. The NS group received prefabricated volar neutral wrist splint during the night for 5 weeks. Outcomes were assessed at baseline and the end of treatment protocol by Boston Carpal Tunnel Scale comprising symptom severity scale (SSS) and functional status scale (FSS). Pain was measured by 100 mm visual analog scale (VAS).*
Results: *VAS decreased more in Acu than in the NS group ($p = 0.028$) whereas improvements in SSS and FSS were not significant between both groups.*
Conclusion: *Electro-acupuncture was as effective as night splinting in respect of overall symptoms and functions in mild-to-moderate degree CTS. However, pain was reduced more by electro-acupuncture than night splinting.*

Keywords: *Hand pain, Hand numbness, Carpal tunnel syndrome, Acupuncture, Splinting*

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Carpal tunnel syndrome (CTS) is regarded as one of the most common entrapment neuropathy. Prevalence in the general population was 0.6-2.1% in men and 3.0-6.8% in women[1,2]. However, higher prevalence was noted in some specific occupational groups requiring high-repetitive hand use or exposing to hand-arm vibrations such as, grinders, butchers, computer users etc[3-6]. Common presentations of CTS include numbness and paresthesia which are frequently nocturnal. In the advanced stage, the patients may suffer from hand weakness and disabilities. Although CTS appears to respond best to surgical release of transverse carpal ligament[7-9], patients might encounter a period of disability during the postoperative recovery[10,11]. In addition, surgical complications may include painful neuroma, complex regional pain syndrome, bowstringing of tendons or unpleasant hypertrophic scars[12]. Thus, some patients prefer to try conservative treatments rather than surgery in the early stage of CTS.

Acupuncture, one of the best recognized complementary and alternative medical treatments[13,14], has been documented generally in Chinese medical literature as an effective treatment of hand numbness and weakness[15-17]. In addition, acupuncture was declared for more than a decade by National Institutes of Health as a useful intervention for CTS[18]. Based on present evidence, acupuncture seems to be a promising intervention for CTS. Its superiority over placebo in CTS has been demonstrated in a number of studies[19-21]. Recently, one randomized controlled trial (RCT) demonstrated that acupuncture is as effective as oral prednisolone in mild-to-moderate CTS[22]. However, oral steroid may be contraindicated or intolerable in some patients.

Hand splinting is frequently prescribed in mild-to-moderate cases of CTS, because its safety and efficacy has been demonstrated and generally accepted[23-26]. To provide scientific evidence for practitioners in choosing a proper treatment for CTS, the authors conducted this RCT to compare the

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efficacy of acupuncture with night splinting in mild-to-moderate degree CTS.

Material and Method

The present study was approved for experimentation on human subjects by the Institutional Review Board, Royal Thai Army Medical Department. All subjects were recruited from Electrodiagnosis Laboratory, Department of Physical Medicine and Rehabilitation, Phramongkutklao College of Medicine, Bangkok, Thailand. Diagnosis and severity grading of CTS were determined by nerve conduction studies based on the American Academy of Neurology clinical diagnostic criteria[27]. Patients were not admitted to the present study if any of the following criteria were present: 1) severe degree CTS, 2) peripheral neuropathy, 3) pregnancy, 4) tendinitis or arthralgia in wrist or hand, 5) obvious space occupying lesion at the wrist, 6) thenar muscle atrophy, 7) history of local steroid injection, 8) history of carpal tunnel surgery, 9) inability to discontinue analgesics, or 10) unwillingness to participate in the present study. Pros and cons of all choices for the treatments of CTS were explained. Individuals who accepted both acupuncture and night splinting were asked to sign informed consent forms. Block randomization was carried out using Stata® program version 10.0 (STATA Corp, LP. College Station, Tx) to allocate subjects into an acupuncture group (Acu) and a night splinting group (NS).

Subjects in the Acu group received acupuncture by a physiatrist who attended a two-year training course from China plus another 4 years of clinical experience. Ten sessions of electro-acupuncture were performed twice a week. Six acupoints including HeGu (LI 4), QuChi (LI 11), DaLing (PC 7), LaoGong (PC 8), and two BaXie points (EX-UE9) were chosen in respect to the meridiens contributing to the affected area (Fig. 1). Sterile disposable acupuncture needles 0.25 mm x 50 mm (Cloud & Dragon®, Jiangsu, China) were inserted into LI4 and LI11 points until DeQi sensation was obtained. The EX-UE9 points were inserted to the depth of 10 mm. To avoid injury to the median nerve and palmar vessels, the PC7 and PC8 points were inserted only to the depth of 1-2 mm in slanting fashion toward the carpal tunnel. All needles except EX-UE9 points were connected with the SDZ-II nerve and muscle stimulator (Hwato®, Suzhou, China) generating 1 Hz continuous direct current for 30 minutes. Subjects in the NS group applied prefabricated volar neutral wrist splints during the night for 5 weeks. The splint restricted flexion motion of the wrist by a metallic bar inserted within the volar aspect of the splint whereas the extension motion was relatively controlled by neoprene and Velcro strap over the dorsal aspect of the hand and forearm (Fig. 2).

All subjects were asked to discontinue analgesics, such as NSAIDs, anticonvulsants or antidepressants for at least one week prior to starting treatment. Only acetaminophen was allowed as a rescue medication.

Hand symptoms were assessed at baseline and immediately at the end of treatments using the Boston Carpal Tunnel Outcome Scales (BCTS). This self-administrated instrument was developed specifically to measure clinical changes in CTS[28].

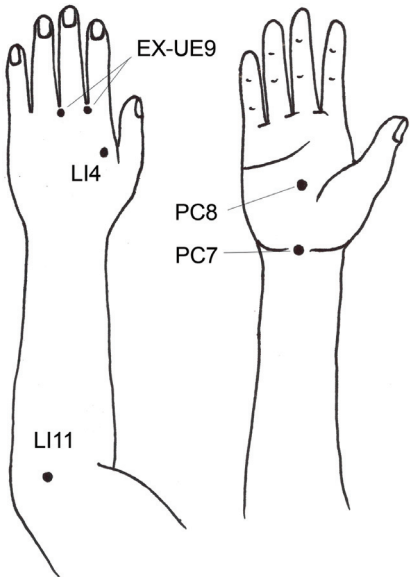

Fig. 1 Locations of acupoints

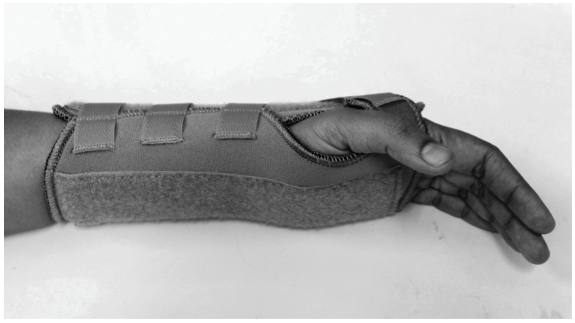

Fig. 2 Prefabricated volar splint used in the study

Its psychometric properties have been generally accepted[29]. BCTS comprises 11 items of Symptom Severity Scale (SSS) measuring pain, paresthesia, numbness, nocturnal symptoms and feeling of weakness plus another 8 items of Functional Status Scale (FSS) measuring difficulties in performing daily activities. Scales ranged from 1-5 representing normal to worst symptoms or disabilities. Reliability of the Thai Version BCTS determined previously showed good internal consistency[30]. Pain severity was measured by 100-millimeter Visual Analog Scale (VAS). In case of bilateral CTS, only the more severe hand was evaluated. Adverse effects of both treatments and analgesics intake during the trial were recorded at the end of treatment protocol.

Statistical analysis

Subjects' characteristics and relevant variables at baseline were expressed as mean $\pm$ SD for continuous variables or as percentage of the group of origin for categorical variables. Comparative analysis of categorical variable was performed using a Chi-square test and continuous variables were analyzed using Independent t-tests. Comparison between Acu and NS groups were using Analysis of Covariance (ANCOVA) for baseline adjusted. All statistical analysis in the present study was performed using STATA version 10.0 (STATA Corp, LP. College Station, Tx). All p-values are two-tailed, and p-value < 0.05 was considered to indicate statistical significance.

Results

Sixty-one subjects were randomized and started treatment (Fig. 3). No difference was found between Acu and NS groups regarding subjects' characteristics and baseline measurements (Table 1). Only one subject in the NS group dropped out for operative treatment. One subject in the NS group required 500 mg of acetaminophen occasionally as a rescue medication.

At the end of treatment protocols, mean BCTS decreased significantly from 1.92 ± 0.54 to 1.53 ± 0.34 in the Acu group ($p < 0.001$) and from 1.88 ± 0.48 to 1.61 ± 0.43 in NS group ($p = 0.007$). In the Acu group, mean scores of SSS, FSS and VAS decreased significantly ($p < 0.05$). In the NS group, mean scores decreased significantly only in SSS ($p = 0.008$) while FSS and VAS did not show significant improvements ($p = 0.154$ and 0.273, respectively).

When outcomes were compared between both groups, the Acu group showed more pain reduction than the NS group ($p = 0.028$), whereas SSS and FSS improvements between both groups were not significantly different ($p > 0.05$). Results are also demonstrated in Table 2. Six of 30 subjects in the Acu group experienced temporary skin bruises at the wrist or elbow due to the small vessel damage. No adverse reaction was found in the NS group. No serious complication occurred in the present study.

Discussion

In the present study, the authors found more apparent pain attenuating effect by acupuncture than night splinting. However, acupuncture was as effective as night splinting in respect to overall symptoms and hand functions. These results are different from a previous study comparing acupuncture with oral prednisolone showing no different outcomes except a better nocturnal awakening symptom in the acupuncture group[22]. In the present study, electro-acupuncture improved all outcomes especially pain which was reduced approximately 58% from baseline. These findings are relevant to the improvement of nerve conduction property after laser acupuncture demonstrated in the previous study[21]. Five weeks of night splinting improved only overall symptoms

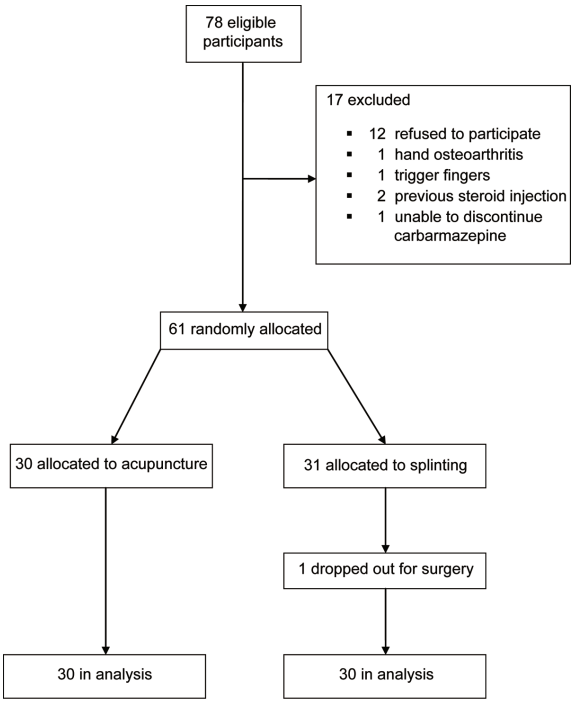

Fig. 3 Participant flow in the study

Table 1. Demographic data and baseline measurements

	Acupuncture (n = 30)	Night splinting (n = 30)	p-value
Age (years)	50.37 ± 9.01	51.73 ± 8.92	0.557
Female (%)	86.67	93.33	0.389
Onset (months)	12.12 ± 15.71	8.32 ± 7.68	0.241
Mild degree (%)	30.0	26.67	0.774
Bilateral (%)	70.0	60.0	0.417
BCTS (1-5 points)	1.92 ± 0.54	1.88 ± 0.48	0.780
SSS (1-5 points)	2.03 ± 0.61	1.98 ± 0.56	0.750
FSS (1-5 points)	1.76 ± 0.63	1.70 ± 0.57	0.728
VAS (0-100 mm)	22.57 ± 22.27	22.57 ± 26.09	1.000

BCTS = Boston carpal tunnel outcome scales; SSS = symptom severity scale; FSS = functional status scale; VAS = visual analog scale

Table 2. Comparison between acupuncture and night splinting groups

	Acupuncture (n = 30)	Night splinting (n = 30)	Difference (95% CI)	p-value
SSS (1-5points)				
Baseline	2.03 ± 0.61	1.98 ± 0.56		
End of treatment	1.57 ± 0.39	1.66 ± 0.50		
Difference[a]	0.46 ± 0.52	0.32 ± 0.61	0.11 (-0.10 to 0.33)	0.295
FSS (1-5points)				
Baseline	1.76 ± 0.63	1.70 ± 0.57		
End of treatment	1.50 ± 0.39	1.54 ± 0.48		
Difference[a]	0.25 ± 0.53	0.17 ± 0.62	0.05 (-0.16 to 0.25)	0.663
VAS (0-100 mm)				
Baseline	22.57 ± 22.27	22.59 ± 26.09		
End of treatment	7.97 ± 14.99	17.60 ± 22.37		
Difference[a]	14.60 ± 19.31	4.97 ± 24.37	9.63 (1.07 to 18.20)	0.028

[a] Baseline adjusted by analysis of covariance (ANCOVA)

without significant benefits of pain and functional improvements. These results differ from the previous reports showing a significant improvement of 0.41-0.53 in FSS[26,31]. Longer splinting duration may attribute to better results in those reports.

Acupuncture reduces pain by stimulating CNS to release a series of neurotransmitters, most importantly opioid peptides and serotonin[32-34]. However, which mechanism attributes to improvements in numbness and median nerve conduction property has not yet been investigated. Regarding the basis of microvascular insufficiency of the median nerve in CTS, local circulation enhancing effect of acupuncture might be a possible mechanism[35-38]. Recently, Napadow V et al[39] found less separation of digit 2 and 3 cortical representing areas from fMRI of CTS patients. Interestingly, the separation increased with the decrease of paresthesia after receiving acupuncture[40]. These findings might be the evidence of brain plasticity of CTS patients' cortical function after acupuncture.

All subjects who enrolled in the present study were clear of any other co morbidities such as trigger fingers or, osteoarthritis. In addition, subjects who previously underwent steroid injection were also excluded. Patients in such cases might respond to acupuncture differently. Diverse acupuncture techniques range from different acupoints chosen, depth of insertion or even needle biomaterial[41]. To the authors' knowledge, some experienced Chinese acupuncturists prefer the "Tou Zhen" style which is a technique of deep needling from the DaLing point

(PC7) in the wrist, probably through the carpal tunnel, toward the LaoGong point (PC8) in the palm. Since median nerve injury due to acupuncture has been reported[42], the authors chose superficial needling technique instead. However, the "Tou Zhen", as well as other acupuncture techniques, might produce different outcomes. According to the results of the present study, acupuncture seems to be a proper choice for CTS patients who suffer dominantly from hand pain. Although the pain symptom is not the main problem in the majority of CTS patients, it occurs in some patients so that an analgesic is required. For individuals who suffer from other symptoms, such as numbness, splinting seems to be a more appropriate option because it is as effective as acupuncture with fewer hospital visits.

Limitations of the present study include the lack of assessment of subjects' expectation to both treatments, which may have affected the study outcomes[43,44]. The present unblinded study may be at risk of assessment bias. However, the self-administered questionnaire used in the present study may minimize this risk for BCTS, SSS and FSS assessment. Since BCTS assessed only the more severely affected hands in case of bilateral CTS, the less severely affected hand that may have responded better could not be assessed. The authors suggest that numbness symptom in subjects with bilateral lesions should be measured independently in both hands with an objective instrument such as monofilaments. Intermediate and long term effects of acupuncture on CTS should be investigated in the future.

Conclusion

Electro-acupuncture provides more pain attenuating effect than night splinting in mild-to-moderate degree CTS. Electro-acupuncture is as effective as night splinting in respect to overall symptoms and functional improvement.

Acknowledgements

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ประสิทธิผลของการฝังเข็มเปรียบเทียบกับการใส่เฝือกอ่อนเวลากลางคืนในการรักษากลุ่มอาการอุโมงค์ข้อมือ: การทดลองแบบสุ่มตัวอย่าง

วิภู กำเหนิดดี, อัจฉรี แก้วทอง

วัตถุประสงค์: *เพื่อเปรียบเทียบประสิทธิผลของการฝังเข็มกับการใส่เฝือกอ่อนเวลากลางคืน ในการรักษากลุ่มอาการอุโมงค์ข้อมือ (CTS)*

วัสดุและวิธีการ: *ทำการศึกษาที่โรงพยาบาลพระมงกุฎเกล้า ประเทศไทย กลุ่มตัวอย่างผู้ป่วย CTS ระดับน้อยถึงปานกลาง จำนวน 61 ราย อายุ 27-67 ปี ได้ถูกแบ่งเป็น 2 กลุ่มด้วยวิธีการสุ่มตัวอย่าง กลุ่มฝังเข็มได้รับการฝังเข็มกระตุ้นไฟฟ้าสัปดาห์ละ 2 ครั้ง ทั้งหมด 10 ครั้ง กลุ่มเฝือกอ่อน ให้ใส่เฝือกอ่อนเพื่อประคองข้อมือตอนกลางคืนเป็นเวลา 5 สัปดาห์ วัดผลโดยใช้แบบสอบถามบอสตัน ซึ่งจะวัดความรุนแรงของอาการ (SSS) และความสามารถในการใช้มือ (FSS) วัดระดับความปวดโดยใช้ visual analog scale (VAS) 100 มิลลิเมตร*

ผลการศึกษา: *VAS ลดลงในกลุ่มฝังเข็ม มากกว่ากลุ่มเฝือกอ่อน (p = 0.028) ขณะที่คะแนน SSS และ FSS ที่ดีขึ้นระหว่างสองกลุ่มไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ*

สรุป: *การฝังเข็มกระตุ้นไฟฟ้ามีประสิทธิผลลดอาการโดยรวม และเพิ่มความสามารถในการใช้มือ ได้เท่ากับการใส่เฝือกอ่อน แต่อาการปวดมือลดลงในกลุ่มฝังเข็มมากกว่ากลุ่มใส่เฝือกอ่อน*