นิพนธ์ต้นฉบับ

Comparative Effectiveness of Acupuncture and Tramadol for Treatment of Acute Ankle Injury

Nopmanee Tantivesruangdet, M.D.*, Chayanin Vejaphuti, M.D.**, Sukrom Cheechareoan, M.D.***
*Emergency Department, Rajavithi Hospital, College of Medicine, Rangsit University, Bangkok, Thailand
**Department of Physical Medicine and Rehabilitation, Rajavithi Hospital, College of Medicine, Rangsit University, Bangkok, Thailand
***Department of Orthopedics, Rajavithi Hospital, College of Medicine, Rangsit University, Bangkok, Thailand
(E-mail: nokyoong12003@gmail.com)
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บทคัดย่อ: การเปรียบเทียบประสิทธิผลการฝังเข็มและยาทามาดอลในการรักษาอาการบาดเจ็บข้อเท้าเฉียบพลัน

นพมณี ตันติเวทเรืองเดช พ.บ., ชญานิน เวชภูติ พ.บ., สุกรม ชีเจริญ พ.บ.
*กลุ่มงานเวชศาสตร์ฉุกเฉิน โรงพยาบาลราชวิถี วิทยาลัยแพทย์ศาสตร์ มหาวิทยาลัยรังสิต กรุงเทพมหานคร ประเทศไทย
**กลุ่มงานเวชศาสตร์ฟื้นฟู โรงพยาบาลราชวิถี วิทยาลัยแพทย์ศาสตร์ มหาวิยาลัยรังสิต กรุงเทพมหานคร ประเทศไทย
***กลุ่มงานออร์โธปิดิกส์ โรงพยาบาลราชวิถี วิทยาลัยแพทย์ศาสตร์ มหาวิทยาลัยรังสิต กรุงเทพมหานคร ประเทศไทย

ภูมิหลัง: การบาดเจ็บข้อเท้าเฉียบพลันเป็นปัญหาและพบได้บ่อยในในการบาดเจ็บกระดูกและกล้ามเนื้อของประชากรทั่วไปการฝังเข็มเพื่อการรักษา ลดอาการปวดและการอักเสบเป็นทางเลือกหนึ่งตามคำแนะนำขององค์การอนามัยโลก **วัตถุประสงค์:** ศึกษาประสิทธิผลของการลดปวดด้วยการฝังเข็ม เปรียบเทียบกับการฉีดยาทามาดอลฉีดเข้ากล้ามเนื้อ ในกลุ่มผู้ป่วยที่มีการบาดเจ็บข้อเท้าเฉียบพลันภายในหนึ่งสัปดาห์ **วิธีการ:** เป็นการศึกษาแบบวิจัยเชิงทดลองทางคลินิก (clinical trial) ในการรักษาผู้ป่วยที่มีการบาดเจ็บข้อเท้าเฉียบพลัน ที่ได้รับการวินิจฉัยว่ามีบาดเจ็บของเส้นเอ็นและเนื้อเยื่อ โดยไม่มีการแตกหักของกระดูก จากการประเมินการบาดเจ็บข้อเท้าตามกฎของออสตาวาและเอกซเรย์ข้อเท้ามีค่าคะแนนความเจ็บปวดมากกว่า 6 คะแนน และได้รับการรักษาด้วยวิธีฝังเข็มหรือฉีดยาทามาดอลเข้ากล้ามเนื้อ ในผู้บาดเจ็บจำนวน 72 ราย อายุ 14 ปีขึ้นไป โดยผู้บาดเจ็บจะได้รับการประเมินอาการปวดตาม Visual Analog Scale (VAS) score ตั้งแต่ก่อนการรักษาและหลังการรักษาที่เวลา 10 นาที 20 นาที 30 นาที 1 สัปดาห์ และ 4 สัปดาห์ **ผล:** ผู้บาดเจ็บข้อเท้าทั้งหมดที่มารับการรักษา มีอายุเฉลี่ย 32.15 ± 12.62 ปี เป็นเพศหญิงร้อยละ 62.5 มีการบาดเจ็บข้อเท้าระดับสองร้อยละ 66.70 บาดเจ็บข้อเท้าข้างซ้ายร้อยละ 52.8 และ สาเหตุการบาดเจ็บไม่ใช่อุบัติเหตุทางจราจรร้อยละ 70.8 มีค่าดัชนีมวลกายเฉลี่ย 23.52 ± 5.27 กิโลกรัมต่อตารางเมตรประสิทธิผลของการรักษาโดยการฝังเข็มต่างจากการฉีดยาทามาดอลเข้ากล้ามเนื้อพบว่าการฝังเข็มช่วยลดอาการปวดของข้อเท้าได้ดีกว่าการฉีดยาทามาดอลในช่วงเวลา 10 นาที 20 นาที 30 นาที และหนึ่งสัปดาห์ แต่ที่เวลาสี่สัปดาห์อาการปวดลดลงไม่แตกต่างกัน นอกจากนี้พบว่า จำนวนผู้บาดเจ็บที่รักษาด้วยการฝังเข็ม ที่มีคะแนนความเจ็บปวดลดลงตาม VAS score น้อยกว่า 4 มีจำนวนมากกว่ากลุ่มที่รักษาด้วยทามาดอลที่เวลา 20 นาที 30 นาทีและหนึ่งสัปดาห์ อย่างมีนัยสำคัญ **สรุป:** การฝังเข็มสามารถลดความเจ็บปวดที่ข้อเท้าจากการบาดเจ็บข้อเท้าเฉียบพลันได้ดีกว่าการรักษาด้วยการฉีดยาทามาดอล ภายในเวลา 20 นาที อย่างมีนัยสำคัญทางสถิติ

คำสำคัญ: Acute ankle injury, VAS pain score, Acupuncture, Tramadol, Ottawa Ankle Rules

Abstract

Background: Acute ankle injuries are common musculoskeletal problem in the general population. Acupuncture is an alternative treatment for acute ankle sprain, and the World Health Organization has recommend edits use for relief of musculoskeletal pain. **Objective:** The objective of this study was to study the effectiveness of acupuncture compared with intramuscular tramadol

in treatment of patients with acute ankle injury within 1 week. **Methods:** This was a clinical trial of 72 patients, aged over 14 years, who presented with acute ankle injury or partial tear of tendon without fracture diagnosed by Roentgenogram, who pain score more than 6 were treated by acupuncture or tramadol. Visual analog scale pain score was assessed before and after treatment with acupuncture or tramadol at the time of the first treatment, after 0 minutes, and then after 10, 20, 30 minutes, 1 week and 4 weeks. **Results:** The mean age of the patients was 32.15 ± 12.62 years old, 62.5% were female, 66.70% had ankle sprain grade II, 52.80% had left ankle sprain and 70.8% had a non-road traffic injury. The Body Mass Index was 23.52 ± 5.27 Kg/ m^2.The effectiveness of acupuncture and tramadol in patients with acute ankle injury within 1 week were different. More pain reduction was seen in patients using acupuncture than in patients using tramadol after 10 minutes, 20 minutes, 30 minutes and 1week. No difference in pain reduction was seen at 4 week. Moreover, the patients who had pain scores less than 4 in acupuncture group were more than tramadol group significantly at 20minutes, 30 minutes and one week. **Conclusion:** Treatment of patients with acute ankle injury with acupuncture can relieve pain more than tramadol within 20 minutes with statistical significantly.

Keywords: Acute ankle injury, VAS pain score, Acupuncture, Tramadol, Ottawa Ankle Rules

Introduction

An acute ankle contusion or sprain is one of the most common musculoskeletal injuries in the general population and also in athletes. Acupuncture is frequently used in standard medical treatment in China, Korea, Japan and the United states of America[1,2] and this treatment has been used to reduce pain in China for more than 2,500 years. In 1995, the World Health Organization (WHO) recommended the use of acupuncture for 59 kinds of treatment including pain reduction.[3]

Five hundred and thirty six cases of 12,000 trauma cases per year of patients who came to the Emergency Department (ED) in Rajavithi Hospital (a super tertiary care hospital under the Ministry Of Public Health) were cases of acute ankle injuries. There have been two Cochrane reviews, as well as another a systematic review which have focused on the use of acupuncture for idiopathic headache[4], low back pain[5], and neck pain.[6] The standard treatments for acute ankle sprain are (non-surgical intervention alone) drugs such as tramadol, morphine, and diclofenac. Other non – drug treatments include: Chinese drug patches, hot and cold water, ice packs, oral Chinese herbal medicine and elastic bandages. Tramadol, analgesic drug which act on the brain's perception of pain (cortical area)[7], is a WHO analgesic level class II drug which the effective in treatment of moderate to intense pain from acute ankle injury; furthermore, it is non-addictive and has no gastrointestinal disorder side effects, whereas, there is a 2.5%-4.5% incidence of gastrointestinal disorder effects in Non-Steroidal Anti-Inflammatory Drug (NSAID).[8,9]

A preliminary case report of the use of acupuncture in Rajavithi Hospital found that it achieved good clinical results, that it was safe, and that the patients were satisfied with their treatment.[10]Acupuncture is an alternative medicine therapy for acute ankle sprain.[11-18] The objective of this study was to study the effectiveness of acupuncture compared with intramuscular tramadol in treatment of patients with acute ankle injury within 1 week.

Materials and Methods

The study protocol of this research was approved by Institutional Review Board (IRB) of Rajavithi Hospital.

The clinical trial of acute ankle injury patients was conducted from July 2016 to June 2017 in Rajavithi ED. Patients were considered for enrollment if they were Thai, were aged over 14 years, and presented with acute ankle injury within 72 hours of presentation in need of analgesia.

Patients were excluded from the study if they met any of the following criteria: had previous history of ankle fracture or dislocation; had used anticoagulation medication or had history of bleeding disorder; had skin infection at the acupuncture point; had history of previous analgesia; had initial pain score less than 6 (the score range was 0-10); or were pregnant.

A physician assessed each patient and, if they meet the study entrance criteria, obtained informed consent. The patients were random treatment by either tramadol or acupuncture. Clinical data and characteristic of the patients including age at diagnosis, parity, weight, height, underlying diseases, symptoms, and VAS pain score were

recorded in their case report forms. Sample size was calculated using two independent means formula. The pain score after treatment at 20 minutes in acupuncture group was 3.48 ± 0.92 and in the tramadol group was 4.2 ± 0.91, based on statistics from Rajavithi Hospital's database. With type I error probability of 0.05, this study required a minimum of 26 cases per group. Assessment of pain, swelling, and difficulty in walking was performed using the Ottawa Ankle Rules (OAR).[19,20]

Roentgenogram of the ankle was then taken in order to confirm that there was no fracture or dislocation. The patient's self-assessed pain level was recorded using the Visual Analog Scale (VAS) after 0, 10, 20 and 30 minutes, after treatment of tramadol intramuscular injection 50 mg or acupuncture at the QUIXU (GB-40) point and KUNLUN (BL-60) point. Sterile disposable stainless steel acupuncture needle used were size 0.25X40 mm. and length 1.5 inches manual acupuncture with less manipulate at the QUIXU (GB-40) point depth 0.5-1.5 cun and KUNLUN (BL-60) point depth 0.5-1.0 cun, single needle per one point, needle retention time 30 minutes.[21,22] This study involved a single experienced acupuncturist who had received the certificate, and all patients in both groups were allowed to take acetaminophen (500 mg) amount 20 tablets/ week for intolerable pain. Participants consisted of 72 acute ankle injuries, and 34 patients were treated with tramadol while 38 received acupuncture treatment at the Emergency Department (ED) in Rajavithi Hospital.

Statistical analysis was carried out with The IBM SPSS version 22.0. Continuous variables were expressed as Mean±SD, median (min-max), and percentage. Comparisons of groups were analyzed using student's t-test or Mann-Whitney's rank-sum test, and Chi-squared test was used for categorical variables. Statistical significance for a two-sided test was set at $p< 0.05$.

Results

Seventy-two patients who came to the Emergency Department were enrolled into this study. The mean age was 31.72±12.55 years old, 61.30% of them were female, 66.70% had ankle sprain grade II, 54.7% had left ankle sprains and 72% were non-road traffic injuries. The mean Body Mass Index (BMI) of the patients was 23.59±5.30 Kg/ m^2 (Table1).

Table 1 Demographic data and clinical characteristics of the study population (n=72)

Characteristic	Tramadol (n =34)	Acupuncture (n=38)	Total (n=72)	p-value
Age (years)	29.79±12.00	34.26±12.96	32.15±12.62	0.135
Sex				0.903
Female	21(61.8)	24 (63.2)	45 (62.5)	
Male	13(38.2)	14 (36.8)	27 (37.5)	
BMI (kg/ m^2)	23.10±4.53	23.89±5.89	23.52±5.27	0.526
Grade injury*				0.182
I	14(41.2)	10 (26.3)	24 (33.3)	
II	20(58.8)	28 (73.7)	48 (66.7)	
Side of ankle				0.618
Left	19(55.9)	19 (50.0)	38 (52.8)	
Right	15(44.1)	19 (50.0)	34(47.2)	
Cause of injury				0.442
Road traffic injury	13(38.2)	8 (21.1)	21 (29.2)	
Non road traffic injury	21(61.8)	30 (78.9)	51 (70.8)	

Value are represented as Mean ± SD and number (%), p-value significant at $p< 0.05$

*Grade injury Grade I: mild swelling, no laxity, little ecchymosis of ankle and difficulty in full weight bearing. Grade II: localized swelling, hemorrhage ecchymosis, and anterolateral tenderness abnormal laxity may be mild or absent.

After treatment of the tramadol group at baseline (0),10, 20 and 30 minutes and of the acupuncture group at 10, 20, 30 minutes, clinical pain levels were assessed using the Visual Analog Scale (VAS). The pain score of tramadol group was 7.61 ± 1.0, while that of the acupuncture group was 7.63 ± 0.97 (p<0.123). Ten minutes pain scores were lower in the acupuncture group 4.61 ± 1.00 than in the tramadol group 6.44 ± 1.08 (p<0.001). Similarly, the 20 minutes pain scores of the acupuncture patients were below those of their tramadol counterparts 3.61 ± 0.82 and 4.97 ± 1.11 respectively (p<0.001). The pain score of the acupuncture group were less severe than those of the tramadol one after 30 minutes 3.29 ± 0.96 and 4.24 ± 0.96 (p<0.001). One week pain scores were also lower in the acupuncture group 1.89 ± 1.01and 2.76 ± 0.99 respectively (p<0.001). At four week follow-up, patients receiving tramadol treatment reported pain scores and their acupuncture counterparts 0.82 ± 1.00, and 0.89 ± 1.01 respectively (p=0.765), there was no statistical significant. At follow up after four weeks, there was no significant difference in VAS, as show in (Table 2 and Fig. 1). After acupuncture treatment for four weeks, no adverse events including (skin infection was found).

Table 2 Pain scores between the tramadol and acupuncture groups (n=72)

Pain scores	Tramadol (n =34)	Acupuncture (n=38)	p-value
Baseline (0)	7.26±0.83	7.61±1.00	0.123
10 minutes	6.44±1.08	4.61±1.00	<0.001*
20 minutes	4.97±1.11	3.61±0.82	<0.001*
30 minutes	4.24±0.96	3.29±0.96	<0.001*
1 week	2.76±0.99	1.89±1.01	<0.001*
4 weeks	0.82±1.00	0.89±1.01	0.765

*significant at p< 0.05

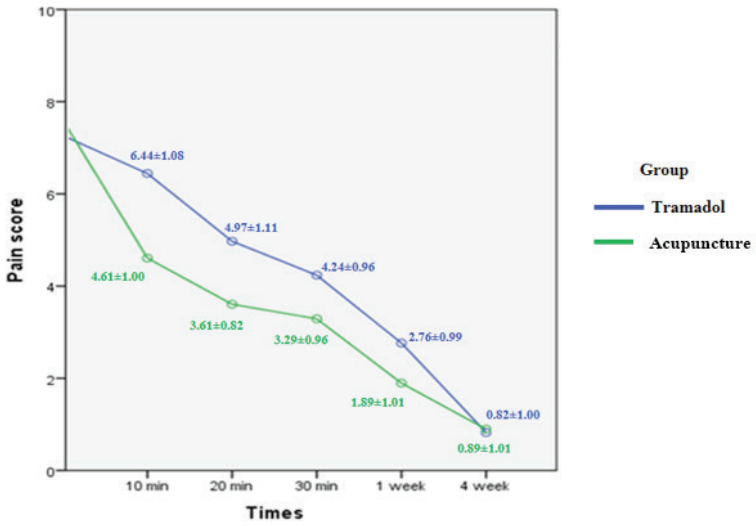

Fig. 1 Comparison pain score between Tramadol and Acupuncture

Table 3 show the number of patients was assessed using VAS score with pain score less than 4 after treatment between the acupuncture and tramadol groups. At 10, 20, 30 minutes, one week and four weeks clinical pain levels. The significant increase number of patients reduction of VAS score until pain score less than 4 after treatment in acupuncture groups at 20 minutes 23.7% (p=0.003), 30 minutes 42.1% (p=0.001), One week 92.1% (p=0.002).

Table 3 Number of patients with pain score less than 4 between the tramadol and acupuncture groups (n=72)

Pain scores less than 4	Tramadol (n =34)	Acupuncture (n=38)	p-value
Baseline (0)	0 (0.0)	0 (0.0)	N/A
10 minutes	0 (0.0)	2 (5.3)	0.495
20 minutes	0 (0.0)	9 (23.7)	0.003*
30 minutes	2 (5.9)	16 (42.1)	<0.001*
1 week	21 (61.8)	35 (92.1)	0.002*
4 weeks	34 (100.0)	38 (100.0)	N/A

*significant at p< 0.05

The patients were able to walk without gait aid and no gastrointestinal side effects were found after tramadol treatment. The outcomes showed that more rapid pain relief was achieved in acupuncture patients at 10, 20 and 30 minutes than in those taking tramadol, according to the patients.[23]

Discussion

Previous studies have shown that acupuncture is effective in treatment of acute low back pain. This study showed that acupuncture treatment is adequately effective in controlling pain and swelling in acute ankle sprain, with pain scores decreasing significantly after treatment at baseline, after 10, 20, and 30 minutes and also after one week, and acupuncture is therefore an effective intervention for acute ankle sprain. This type of pain management is contraindicated for patients with bleeding disorders and those who are pregnant. In another study, patients were divided into 2 groups, and35 patients with acute ankle injury were treated with acupuncture alone while another 70 patients with ankle injury were treated with acupuncture in addition to pharmacotherapy.[23] The study was aimed at for providing treatment of pain at ED. The results showed that acupuncture is more effective in the treatment of acute ankle injury concordant with Cohen[24], and Park[13] study found that using the acupuncture as an alternative or an add-on to other treatment for acute analgesia.

Conclusion

In acute ankle injury patients, greater reduction in pain after 10 minute was found following acupuncture treatment. Pain reduction achieved using acupuncture was significantly greater than the obtained using tramadol at 10, 20 and after 30 minutes and after one week. At four weeks, there was no significant difference in pain reduction between the two treatments. Acupuncture is effective in treating of acute ankle injury in ED and it is a safe form of treatment. The effectiveness of acupuncture treatment decrease pain at 10 minutes (22.40%) to one week (31.52%). Further studies should be performed to assess a large number of cases in multicenter treatment with a comparison of acupuncture and another standard treatment group. However, the placebo effect from acupuncture cannot be controlled.

What this study adds

Acupuncture showed good outcomes for pain relief in acute ankle injury cases, together with good levels of patient satisfaction toward its rapid effectiveness. Acupuncture can serve as an alternative treatment in acute ankle injury at ED, especially in cases of patients with known drug allergies.

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