Electroacupuncture for Tension-type Headache on Distal Acupoints Only: A Randomized, Controlled, Crossover Trial

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Objective.—To investigate the efficacy of electroacupuncture, applied to distal acupoints only, for tension-type headache.

Background.—Electroacupuncture is commonly used for tension-type headache, but when applied to distal acupoints only, evidence of its efficacy is lacking.

Design.—A randomized, single-blinded, sham-controlled, crossover clinical trial.

Methods.—The trial had 5 stages: baseline (2 weeks), phases I and II (each 4 weeks), washout period (2 weeks), and follow-up (3 months after phase II). Forty patients were randomly assigned to either group A or group B. Group A received real electroacupuncture during phase I, then sham electroacupuncture in phase II. Group B received the treatments in reverse order. Outcome measures were headache frequency and duration, pain intensity using a visual analog scale, mechanical pain threshold, headache disability, and sickness impact. Data were analyzed by univariate 2-way analysis of variance.

Results.—Thirty-seven patients completed the trial. There were no significant differences between the 2 groups at baseline. At the end of phase I, group A, but not group B, demonstrated significant improvement in mean (standard error of the mean [SEM]) headache frequency (3.0 per month [0.3] versus 12.0 per month [1.7]), duration (13.3 hours [3.5] versus 32.0 hours [6.2]), pain intensity (32.8 mm [4.1] versus 47.5 mm [2.7]), pain threshold (right side, 2.9 kg/second [0.1] versus 0.9 kg/second [0.1]; left side, 2.4 kg/second [0.1] versus 1.1 kg/second [0.1]), headache disability score (6.0 [1.0] versus 16.3 [1.6]), and sickness impact score (288.7 [48.0] versus 687.1 [77.2]). For each parameter, significant differences also were demonstrated for both groups between baseline and phase II, and baseline and follow-up. There were no significant differences between the groups at the end of follow-up (P > .05).

Conclusion.—Electroacupuncture to distal points alone is effective for short-term symptomatic relief of tension-type headache.

Key words: electroacupuncture, tension-type headache, acupuncture analgesia, Chinese medicine

Abbreviations: TTH tension-type headache, CM Chinese medicine, TENS transcutaneous electrical nerve stimulation, VAS visual analog scale, PTH pain threshold, HDI headache disability index, SIP sickness impact profile, SEA sham electroacupuncture, REA real electroacupuncture, EA electroacupuncture

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Tension-type headache (TTH) is a common condition that affects over three quarters of the world population; however, the severity of the condition varies, with approximately 16% of those affected consulting their physicians and 4% receiving treatment. Tension-type headache also has a substantial socioeconomic impact. The first-line treatment for TTH is drug therapy using aspirin, ibuprofen, and naproxen; however, unwanted side effects have been reported including epigastric discomfort, drowsiness,
Other therapies include relaxation, biofeedback-assisted relaxation, and cognitive therapy. Each involves specific patient training. There is evidence of beneficial effects of these therapies, however, their efficacies are yet to be confirmed and there are high costs involved.

Existing literature suggests that TTH may be effectively managed by using acupuncture to both local and distal acupoints. Furthermore, acupuncture for 4 weeks has been reported to produce effective relief for up to 5 months. There are a number of methodological weaknesses, however, in the studies reported. Firstly, all of the studies used local points and 1 or 2 distal acupoints. In Chinese medicine (CM), acupoints on the limbs, especially those below the elbow and knee joints, are relevant for both local and systematic disorders. The use of both local and distal points makes it impossible to assess the contribution of each to any effect observed. Secondly, most studies have employed mock transcutaneous electrical nerve stimulation (TENS) as a sham acupuncture control. Mock TENS produces no sensation, and hence patients are often not effectively kept unaware of the type of treatment given.

The present study investigated the efficacy and persistence of demonstrated beneficial effects of acupuncture applied only to extremity (distal) acupoints to treat TTH.

**METHODS**

This study was conducted at the Research Clinic of the RMIT Chinese Medicine Research Group at the Bundoora Campus, RMIT University, Melbourne, Australia. Research protocol was approved by the RMIT Human Research Ethics Committee according to guidelines set by the National Health and Medical Research Council (NHMRC) of Australia.

**Patients.**—Patients were recruited from the local community in the northern suburbs of Melbourne through advertisements in local newspapers. Respondents to the advertisements were asked to complete a screening questionnaire and to attend an interview at the research clinic. During the initial visit, a clinical history was taken and a comprehensive physical examination was performed by a qualified practitioner of CM for assessing eligibility. Those with one or more of the following conditions were excluded: classic or common migraine, brain tumor, arterial hypertension, eye problems related to headache, trauma-induced headache, or pregnancy. Those who met the inclusion criteria of the International Headache Society (IHS) for episodic and chronic TTH were accepted into the study (Table 1). Informed consent was obtained and information related to the objectives and procedures of the study were provided to all patients.

Those eligible then entered a 2-week baseline phase before beginning the treatment phases. Baseline assessments included headache frequency and duration, pain intensity using a visual analog scale (VAS), mechanical pain threshold (PTH), headache disability index (HDI), and sickness impact profile (SIP).

**Selection of Acupoints.**—A CM diagnostic procedure was performed for all patients to guide the subgrouping and acupuncture point selection. Details are included in Table 2.

**Study Design and Treatment Procedure.**—Each patient was randomly assigned to either group A or group B by drawing an envelope containing a randomization number generated by a computer program. All
patients were informed that there was a 50% chance of receiving sham electroacupuncture (SEA) treatment during phase I (see below). Patients were required to attend the clinic for treatment twice a week for a period of 4 weeks (phase I). Then, after a 2-week washout period, the 2 groups were crossed over to receive the alternate treatment twice weekly for another 4 weeks (phase II).9 Group A had real electroacupuncture (REA) in phase I, then SEA in phase II. Group B had SEA in phase I, then REA in phase II. A 3-month follow-up was undertaken after completion of phase II. The protocol for the trial is presented in Figure 1.

During treatment, patients were required to be in a supine position. Needle sites were disinfected, and disposable needles were inserted into the acupoints selected with guiding tubes. For REA, manipulation was performed so that the patients could gain the De Qi sensation of acupuncture, described as a numb, distended, slight aching sensation.19 A battery-operated EA instrument (Model MME 501, Meyer Medical Electronics, Australia) was connected to the handles of acupuncture needles to provide electrical stimulation for 30 minutes. Continuous stimulation, with frequencies of 2 Hz and 100 Hz, was applied at alternate sessions of treatment. The alternation of the frequency of stimulation was to prevent development of tolerance to treatment.20,21 Low- (0.2 volts) or high- (1.5 volts) intensity stimulation was applied on the basis of the CM diagnosis (Table 2), the low-intensity stimulation being applied for deficient syndromes, and the high-intensity stimulation for excessive syndromes.20

For SEA, needles were inserted into points that were 5 to 10 mm away from the correct acupuncture locations and maintained at a superficial level of insertion to minimize stimulation.13 No further manipulation was performed. The SEA was continuous low-frequency (0.2 Hz) and low-intensity (0.1 volt) stimulation delivered by a modified MME 501 acupuncture instrument. For both REA and SEA, electrical stimulation was monitored by an indicator light throughout the treatment period. To ensure the integrity of blinding, the acupuncturist did not discuss the acupuncture procedure with the patients.

Outcome Measures.—**Frequency, Duration, and Intensity of Headache.**—A questionnaire relating to the frequency and duration of headache was completed by all patients on 4 occasions: at the beginning of the baseline period, at the end of the phase I and phase II treatment periods, and at the end of the follow-up period. In respect of headache frequency, patients were asked to indicate how often they experienced

Table 2.—Selection of Acupoints Based on Chinese Medicine

<table>
<thead>
<tr>
<th>Patterns</th>
<th>Acupuncture Point Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>External wind and phlegm (excessive syndrome)</td>
<td>Hegu (LI4), Waiguan (SJ5), Fenglong (ST40), and Kunlun (GB60)</td>
</tr>
<tr>
<td>Blood stasis (excessive syndrome)</td>
<td>Taichong (LR3), Xingjian (LR2), Hegu (LI4), and Lieque (LU7)</td>
</tr>
<tr>
<td>Deficiency of kidney Jing, Qi, and blood (deficient syndrome)</td>
<td>Saninjiao (SP6), Zusanli (ST36), Hegu (LI4), and Waiguan (SJ5)</td>
</tr>
<tr>
<td>Hyperactive yang of liver (excessive syndrome)</td>
<td>Taichong (LR3), Hegu (LI4), Taixi (KI3), and Waiguan (SJ5)</td>
</tr>
</tbody>
</table>

![Fig 1.—Subject progression through stages of trial. REA indicates real electroacupuncture; SEA, sham electroacupuncture.](image-url)
headaches from the highest prevalence (1 to 2 times a day) to the lowest (1 or 2 times a month). Regarding headache duration, patients were asked how long each attack of headache lasted, ranging from 30 minutes to 7 days. For each patient, mean values of headache frequency and duration were calculated for each of the baseline, phase I, and phase II periods. Headache intensity was recorded by patients daily during the baseline, phase I, and phase II periods and throughout the follow-up period. The VAS ranged from 0 (no pain) to 100 (highest level of pain). The questionnaires and VAS forms were returned to a research assistant who was unaware of patient grouping.

**Mechanical Pain Threshold.**—To estimate PTH, a trained research assistant applied an algometer on points at the frontal, suboccipital, posterior cervical, masseter, and temporalis muscles, bilaterally, increasing the pressure steadily at a rate of 0.5 kg/second until patients reported a painful sensation. This measurement was performed at the beginning of the baseline period and at the end of each of the phase I, phase II, and follow-up periods. Data entry forms were returned to the research assistant.

**Quality-of-Life Questionnaires.**—The SIP and HDI were self-administered to assess the patient’s level of function and quality of life.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Group A (n = 20)</th>
<th>Group B (n = 20)</th>
<th>t &lt;sub&gt;38&lt;/sub&gt; Result</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>42.6 (1.8)</td>
<td>41.5 (1.9)</td>
<td>0.41</td>
<td>.68</td>
</tr>
<tr>
<td>Sex, No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of headache, No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Episodic</td>
<td>9</td>
<td>9</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>Chronic</td>
<td>11</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History, y</td>
<td>11.4 (0.8)</td>
<td>11.1 (0.8)</td>
<td>0.23</td>
<td>.83</td>
</tr>
<tr>
<td>Frequency/mo</td>
<td>13.8 (1.7)</td>
<td>12.5 (1.6)</td>
<td>−0.45</td>
<td>.68</td>
</tr>
<tr>
<td>Duration, h</td>
<td>47.7 (7.4)</td>
<td>40.8 (4.8)</td>
<td>−0.39</td>
<td>.7</td>
</tr>
<tr>
<td>Intensity, mm</td>
<td>45.2 (2.4)</td>
<td>49.3 (2.4)</td>
<td>−1.21</td>
<td>.23</td>
</tr>
<tr>
<td>Pain threshold, kg/second</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right side</td>
<td>1.2 (0.1)</td>
<td>1.0 (0.1)</td>
<td>1.42</td>
<td>.16</td>
</tr>
<tr>
<td>Left side</td>
<td>1.0 (0.1)</td>
<td>1.1 (0.1)</td>
<td>0.64</td>
<td>.53</td>
</tr>
<tr>
<td>Headache disability index</td>
<td>17.0 (2.1)</td>
<td>18.4 (1.6)</td>
<td>−0.49</td>
<td>.63</td>
</tr>
<tr>
<td>Sickness impact profile</td>
<td>735.3 (138.8)</td>
<td>810.8 (109.6)</td>
<td>−0.43</td>
<td>.67</td>
</tr>
</tbody>
</table>

*Values are mean (standard error of the mean) unless otherwise indicated.
versus chronic), and baseline measures of headache frequency, duration, intensity, PTH, HDI, and SIP. There were no statistically significant differences in these parameters between the 2 groups. Three patients (1 from group A and 2 from group B) failed to return their follow-up assessment and were excluded from follow-up data analysis.

**Frequency of Headache.**—Group A reported significantly fewer headaches (3.0 per month [0.3]) than group B (12.0 per month [1.7]) at the end of phase I ($P < .001$), but not at the end of phase II (Figure 2A).

Within each group, frequency of headache was reduced at the end of the REA treatment period; that is, at the end of phase I for group A ($P < .001$) and at the end of phase II for group B ($P < .01$) when compared with baseline values. Post hoc analyses revealed that the frequency of headache of group A at the end of phase II (1.2 per month [0.3]) was also significantly less than the baseline value (13.8 per month [1.7]). This suggests that the reduction of headache frequency after REA of group A during phase I was maintained through the washout period and phase II (SEA treatment). In group B, headache frequency was significantly less on the completion of phase II (REA) (2.8 per month [1.1]) than both at baseline (12.5 per month [1.6]) and at the end of phase I (SEA) (11.9 per month [1.7]) (Figure 2A).

At the end of the 3-month follow-up, group A reported significantly less frequent headaches (4.2 per month [0.9]) than group B (9.5 per month [2.1]). In both groups, headache frequency at the end of the follow-up was significantly less than the respective baseline value ($P < .001$). In both groups, however, frequency at the end of follow-up was significantly higher than at the end of phase II ($P < .05$).

**Duration of Headache.**—The findings for headache duration were similar to those for headache frequency (Figure 2B). Group A had a significantly shorter headache duration at the end of both phase I (13.3 hours [3.5]) and phase II (6.3 hours [2.5]), compared with the baseline value (47.7 hours [7.4]). In group B, duration of headache was significantly shorter at the end of phase II (5.7 hours [2.6]), than both at baseline (40.8 hours [4.8]) and at the end of phase I (32.0 hours [6.2]). Although the mean duration of headache for group A was significantly shorter than that for group B at the end of phase I, there was no significant difference in headache duration between the 2 groups at the end of phase II.

At the end of the follow-up period, duration of headache was significantly greater in both groups (group A, 28.4 hours [5.8]; group B, 38.8 hours [6.1]), than the respective value in phase II (group A, 6.3 hours [2.5]; group B, 5.7 hours [2.6]).

**Intensity of Headache.**—The intensity of headache was also reduced in both groups by REA treatment ($P < .001$) (Figure 2C). In group A, the
Intensity of Headache

Baseline Phase I Phase II Follow-up

Visual Analog Scale (mm)

Group A
Group B
#

Fig 2C.—Intensity of headache. *Significant difference between data obtained at follow-up and phase II for both groups (analysis of variance, \( P < .05 \)).

baseline VAS was 45.2 mm [2.4], and the mean value during phase I was 32.8 mm [4.1] and during phase II, 20.5 mm [4.5]. In group B, the mean baseline was 49.3 mm [2.4]; phase I, 47.5 mm [2.7]; and phase II, 23.6 mm [4.5].

At the end of the 3-month follow-up, the mean intensity of headache increased in both groups compared with values at the end of phase II \((P < .001)\), but in both groups the mean VAS scores remained lower than the respective baseline scores \((P < .05)\).

Mechanical Pain Threshold.—The PTH increased during the treatment periods \((P < .001)\) (Table 4; Figure 2D). Overall, group A’s PTH was significantly higher than that of group B \((P < .001)\). Post hoc analyses showed that group A had a higher PTH on both sides of the head than group B at the end of both phase I and phase II. Within each group, PTHs measured on both sides of the head were similar at each time of measurement.

Quality of Life.—The REA decreased SIP scores in both groups \((P < .001)\), suggesting an improvement of quality of life. The SIP scores at the end of phase I were lower in group A (288.7 [48.0]) than in group B (687.1 [77.2]) \((P < .001)\), but there was no difference in the scores between the 2 groups at the end of phase II (group A, 153.1 [37.3]; group B, 239.7 [37.0]) (Figure 3).

Changes in the HDI score were similar to those of the SIP; that is, it reduced during the REA treatment period in both group A and group B (phase I: group A, 6.0 [1.0] versus group B, 16.3 [1.6]; phase II: group A, 3.0 [0.7] versus group B, 3.6 [0.6]) \((P < .001)\) (Figure 3).

Table 4.—Mechanical Pain Thresholds

<table>
<thead>
<tr>
<th></th>
<th>Group A (n = 20)</th>
<th>Group B (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Right side</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.2 (0.1)</td>
<td>1.0 (0.1)</td>
</tr>
<tr>
<td>Phase I</td>
<td>2.9 (0.1)</td>
<td>0.9 (0.1)</td>
</tr>
<tr>
<td>Phase II</td>
<td>3.2 (0.1)</td>
<td>2.6 (0.105)</td>
</tr>
<tr>
<td><strong>Left side</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.0 (0.1)</td>
<td>1.1 (0.1)</td>
</tr>
<tr>
<td>Phase I</td>
<td>2.4 (0.1)</td>
<td>1.1 (0.1)</td>
</tr>
<tr>
<td>Phase II</td>
<td>2.6 (0.1)</td>
<td>2.7 (0.1)</td>
</tr>
</tbody>
</table>

Values are expressed as mean kg/second (SEM).

Fig 2D.—Mechanical pain threshold measured on both sides of head. *Significant difference between the 2 groups (2-sample \( t \) test, \( P < .05 \)).

Fig 3.—Headache Disability Index (HDI) and Sickness Impact Profile (SIP) scores. *Significant difference in HDI and SIP between the 2 groups (unpaired \( t \) test, \( P < .05 \)). †Significant difference in HDI and SIP between data obtained at follow-up and phase II for both groups (analysis of variance, \( P < .05 \)).
At the end of the 3-month follow-up, for both groups, SIP (*P < 0.001) and HDI (*P < 0.001) scores increased from their values in phase II (Figure 3), indicating that the improvement in quality of life was regressing. The SIP and HDI values, however, remained lower in both groups than the respective baseline values (*P < 0.05).

**DISCUSSION**

The results of this study demonstrate that headache frequency, duration, and intensity; pain threshold; and quality of life improve after REA on the distal points only, but not after SEA. Furthermore, the effect diminished after a 3-month follow-up, but there was still improvement compared with the baseline assessment. These findings indicate that REA on distal points only, selected according to CM theory, produces a significantly better outcome than SEA. The effects seem to decrease after 3 months, however, indicating relatively short-term symptomatic relief of headache, confirming findings of previous studies.9,25-27

Unlike other studies, this study attempted to address one of the difficult issues in acupuncture research; that is, to devise a credible sham control to account for placebo and nonspecific effects of therapy. We are aware of other forms of sham control, such as mock TENS that has been widely used in a number of clinical trials.17,28 Mock TENS may not be the most appropriate option for a sham control, however, as it induces no sensation, and may not mimic the nonspecific effects of acupuncture. In contrast, the present study applied sham acupuncture by delivering an electrical stimulation at a lower frequency and a lower intensity through shallowly inserted needles. This approach generates both a perception of skin penetration and an experience of EA stimulation.29

To the best of our knowledge, the current study is the first of its kind using distal acupoints only for treating TTH. Previous clinical trials used 6 to 8 local points on the neck and head regions with 1 or 2 distal points.9,12,27,30,31 The selection of local points is often influenced by findings of tender points in the frontalis, trapezius, temporalis, masseter, and sternocleidomastoid muscles.31,32 Some of these loci are connected to the trigger points for TTH.22 The trigger point dry needling technique is similar to acupuncture on local points. In the current study, EA on distal points on the upper and lower limbs, not only reduced headache, but also increased PTH bilaterally, measured at the neck and facial muscles. Furthermore, the quality of life, as indicated by SIP and HDI scores, was also improved. General changes in pain intensity, PTH, and life quality suggested that EA on distal points only is effective for TTH.

There was further evidence to suggest that distal point acupuncture may improve the quality of life of patients with chronic pain. The understanding of chronic pain is multidimensional involving sensory, affective, and cognitive components.33 Tension-type headache is associated with psychological disturbances such as anxiety and depression.6,34,35 With functional magnetic resonance imaging, Wu and others found that acupuncture on ST36 (leg) and LI4 (hand) (both are distal points) enhanced the activity of the hypothalamus, which contains a center for pain inhibition, and deactivated the limbic system, which is involved in the fight and fright reaction to danger and injury.36 The limbic system has been shown to be highly active during chronic pain.37 Consistent with the findings of the brain image study by Wu et al,36 in healthy humans, acupuncture had been found to reduce anxiety and depression, and, in patients with chronic pain, pain intensity.38,39 The effect of acupuncture on eliminating affective and cognitive components of pain might explain the therapeutic effect observed in the current study.

With regard to the value of the CM theory in point selection, contradictory results have been reported. Both the current study and the study by Irnich and colleagues emphasized the use of the CM theory and both found beneficial effects of acupuncture.25 Two other studies using local points combined with 1 or 2 distal points, but without any emphasis on the application of CM theory, also demonstrated a superior acupuncture outcome compared to sham control.9,27 None of these studies, however, were designed to assess the CM theories in acupoint selection. To answer this question, a multi-arm study including an additional control group using distal acupuncture points, which are nonspecific to the condition treated, may be appropriate.

The second aim of the study was to investigate the persistence of any observed effect of distal
acupuncture. At the end of phase II, both groups had significant pain relief compared with baseline. The pain relief had lessened, however, at the end of the 3-month follow-up. These findings were inconsistent with those of other studies where a prolonged effect of 3 to 5 months was observed.\textsuperscript{12-15} A plausible explanation might be that previous studies used both distal and local points, whereas only distal points were used in the current study. In addition, stimulation of local points may deactivate the trigger points, while stimulation of distal points may enhance pain inhibition and suppress affective aspects of pain.\textsuperscript{36} Thus, these findings suggest that a more appropriate treatment protocol for TTH is one using a combination of both local and distal points. This suggestion, however, is yet to be tested.

It is also worth mentioning that the present study adopted a crossover design to increase statistical power. This design provides each subject control to minimize within-subject variances.\textsuperscript{40} A 2-week washout period was used, based on a previous study;\textsuperscript{9} however, the length of washout might not have been adequate as a regression to baseline was not demonstrated during the washout period. Thus, group A continued to experience significant pain relief after washout and during the phase II period in which SEA was administered.

The duration of the effect of REA in group A extended beyond 19 weeks (6 weeks plus the 3-month follow-up period), with the exact duration being unknown (Figure 2A). In the context of CM, this probably relates to strength and duration of needling, presence of De Qi sensation, frequency, and courses of treatment.\textsuperscript{16}

**CONCLUSION**

This study demonstrated that REA, on distal points only, effectively reduces the frequency of attacks, duration, and intensity of TTH and improves the quality of life, with the effect lasting at least 6 weeks. In addition, the treatment is relatively safe, as no side effects were reported throughout the study.

Further studies should be undertaken to assess the long-term effect of distal acupuncture by repeated measures conducted throughout the follow-up period, instead of only one assessment at the end of 3 months. The methods employed for selection of the acupoints also warrant further investigation.

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**REFERENCES**