

# The effects of laser acupuncture on chronic tension headache – a randomised controlled trial

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## Abstract

**Objective** Headache affects the quality of life for many people throughout the world. Tension headache is among the commonest forms. Acupuncture is the most widely practised non-medicinal treatment for headaches. The purpose of this study was to explore the effects of laser acupuncture in this type of headache.

**Methods** Fifty patients with chronic tension-type headache were randomly allocated to treatment or placebo groups. Patients in the treatment group received low energy laser acupuncture to LU7, LI4, GB14, and GB20 bilaterally. Points were irradiated for 43 seconds, and the intensity was 1.3J (~13J/cm<sup>2</sup>). Ten sessions were given, three per week. The placebo group was treated in a similar way except that the output power of the equipment was set to zero. The outcome variables were headache intensity (VAS), duration of attacks, and number of days with a headache per month, by daily diary, assessed monthly to three months after treatment.

**Results** There were significant differences between groups ( $P < 0.001$ ) in changes from baseline in months one, two and three, in median score for headache intensity (treatment group -5, -3 and -2, placebo group -1, 0 and 0), median duration of attacks (treatment group -6, -4 and -4, placebo group -1, 0 and 0 hours), and median number of days with headache per month (treatment group -15, -10 and -8, placebo group -2, 0 and 0).

**Conclusion** This study suggests that laser acupuncture may be an effective treatment for chronic tension-type headache, but the results should be confirmed in larger and more rigorous trials.

## Keywords

*Acupuncture, chronic tension-type headache, laser acupuncture, low energy laser, randomised controlled trial.*

## Introduction

Every year the lives of many people throughout the world are affected by headaches.<sup>1</sup> Treatment for headaches includes medical and non-medical approaches. Tension headache falls into two categories: chronic and episodic; episodic tension-type headache can be treated with rest and analgesics, while chronic tension-type headache demands a more fundamental treatment.<sup>1</sup> The most widely practised of the non medicinal treatments for headache is acupuncture.<sup>2</sup>

The effects of acupuncture on various types of headache have been studied widely.<sup>3-17</sup> In a Cochrane review, Melchart et al compared the effectiveness of acupuncture with 'sham' (placebo) acupuncture and other interventions used to treat

idiopathic (primary) headaches including tension-type headache.<sup>3</sup> They concluded that the evidence supports the role of acupuncture for the treatment of idiopathic headaches but is not conclusive. While some researchers recommended that acupuncture is valuable for various types of headache, including tension type and migraine,<sup>4-10</sup> others failed to demonstrate clinically significant differences.<sup>11-17</sup>

Factors which make the practice of acupuncture unlikely to be acceptable to certain medical communities include the possibility of transmitting infection, the risk of visceral trauma, particularly pneumothorax, and the invasive nature of the practice in general.<sup>18</sup> Efforts to find proper alternatives for needles began in the middle

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of the 20th century, and one significant suggestion is low energy laser.<sup>19</sup>

Low energy laser by definition has an output power of less than 1W/cm<sup>2</sup>. This type of laser serves the double purpose of tissue repair and pain relief in physical therapy.<sup>20</sup> In this study, low energy laser was used to stimulate headache-related points with the aim of exploring its effect on chronic tension-type headaches.

### Methods

The study was a single blind, randomised, placebo controlled clinical trial performed at three outpatient departments in Isfahan University of Medical Sciences, Iran, from the 9 April to the 21 November 2000.

Ethical approval for the study was obtained from the Isfahan University of Medical Sciences Research Ethics Committee. Patients were selected consecutively by the neurologists of the three outpatient departments, according to the inclusion and exclusion criteria below. After giving informed consent, those who were eligible and willing to participate were assessed by an independent physician. This assessment included a detailed history and collection of baseline data and physical examination. Baseline data included age, sex, previous treatment methods, visual analogue scale (VAS) of headache intensity on a scale from zero (no pain) to 10 (most severe pain), duration of each attack (in hours), and the number of days on which headaches occurred per month since first suffering headaches.

The main inclusion criterion was chronic tension-type headache for which the subject had not received any treatment in the previous two weeks.<sup>21</sup> Patients with other causes of chronic headache were excluded. Patients who had papilloedema, pulsating headaches, asymmetrical pupillary reflexes, neurological deficits, systemic disorders (hypertension or metabolic disorders) or contraindications to treatment (anticoagulation therapy, other simultaneous treatment, localised skin infection, fear of acupuncture) were excluded. An explanation of the acupuncture technique was given to all subjects. All patients were told before randomisation that one of the two treatments might be a sham procedure. Patients took no concomitant analgesics.

At the first visit all patients underwent initial assessment and completed questionnaires. Following this, each patient received laser acupuncture (Group A) or sham laser acupuncture (Group B) three times per week for 10 sessions. The treatment group received low energy laser radiation treatment from Endolaser 476 (Enraf-Nonius, The Netherlands). This unit is of the Gallium-Arsenide-Aluminium (Ga-As-Al) type with an output wave length of 830nm and maximum output intensity of 39mW/cm<sup>2</sup>. The settings and technique of the laser radiation used on each point were: intensity 1.3J (~13 J/cm<sup>2</sup>), output 100%, continuous mode, using vertical contact with pressure and a duration of 43 seconds.

The points for exposure to laser radiation were selected by reference to authoritative sources on acupuncture.<sup>18</sup> These points included four points, two local and two distal: GB14, GB20, LI4 and LU7. Treated bilaterally, this amounts to a total of eight points.

The placebo group received the same intervention as above except that the power output was set to zero during the treatment.

Data were collected from daily diaries that were given to patients at each treatment session and collated by one observer who was aware of group allocation. The assessments were the maximum intensity of the patient's pain in every attack of the headache (VAS), the duration of each attack (in hours), and the number of days with headache in that month, as the primary outcome measures.<sup>16</sup> Three-month follow up was deemed reasonable in order to demonstrate a therapeutic effect, therefore three assessments were made at monthly intervals after the last session. Assessment records were kept separately from records of treatment and documentation.

Our intention was to analyse 22 patients per group; this calculation was based on previous experience of the number of subjects needed to observe a six point difference on the VAS score with a standard deviation (SD) of seven points.

Assessments were made at baseline and monthly up to three months after the last treatment session. The majority of outcome variables were not normally distributed therefore data were summarised using medians and interquartile ranges and for the analysis, the non-parametric

Wilcoxon's test was used. Relative changes in VAS (intensity of headache), the number of days with headache per month, and the duration of headache were calculated for both groups. All calculations were carried out by an independent, blinded statistician using SPSS for Windows version 10.05.

### Results

Fifty patients (40 females and 10 males) fulfilled the inclusion criteria and were randomised. There were no dropouts or withdrawals from the study. The baseline characteristics of the two groups (mean and range) are shown in Table 1. Baseline characteristics of the study sample were equally balanced between groups for most variables, but the control group were older on average ( $P=0.04$ ) and the placebo group had a significantly shorter duration of headache ( $P=0.02$ ). Table 2 summarises the results for the three outcome variables at baseline and at each month up to three months, and Figure 1 shows the changes in median headache VAS in the two groups. There were significant changes over time in both groups. The treatment group was superior to the placebo group in all outcomes at all time points beyond

baseline ( $P<0.001$ ). No adverse effects were reported with either acupuncture or placebo group.

Table 1 Baseline characteristics of participants

	Group A Active	Group B Placebo
Number of patients	25	25
Male : female ratio	1:4	1:4
Mean age (yrs), range	33 (25-52)	38.6* (26-54)
*significant difference (Wilcoxon's tests, $P=0.04$ )		

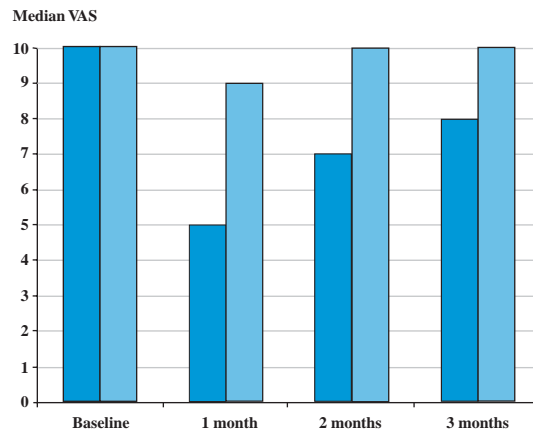


Figure 1 Median headache scores (VAS) reported at different time points by laser ■ and sham laser ■ groups.

Table 2 Median (interquartile range) values for three headache measures at baseline, changes from baseline and comparison between groups

	Group A Active (n=25)	Group B Placebo (n=25)	Difference A-B	P†
<b>VAS</b>				
Baseline	10 (3.0)	10 (1.0)	0	0.1
Changes at 1 month	-5 (3.8)	-1 (2.0)	4	<0.001
Changes at 2 months	-3 (4.0)	0 (1.5)	3	<0.001
Changes at 3 months	-2 (6.3)	0 (0.0)	2	<0.001
<b>Number of days</b>				
Baseline	20 (15.0)	18 (15.0)	2	0.5
Changes at 1 month	-15 (16.5)	-2 (5.0)	13	<0.001
Changes at 2 months	-10 (20.0)	0 (5.0)	10	<0.001
Changes at 3 months	-8 (21.5)	0 (0.0)	8	<0.001
<b>Duration (hours)</b>				
Baseline	10 (4.0)	8 (4.5)	2	0.02
Changes at 1 month	-6 (4.5)	-1 (2.0)	5	<0.001
Changes at 2 months	-4 (6.0)	0 (0.5)	4	<0.001
Changes at 3 months	-4 (7.5)	0 (0.0)	4	<0.001

† Wilcoxon's test

### Discussion

This trial compares three key variables of headache (headache intensity [VAS], days with headache, duration of attacks) in patients with chronic tension-type headache given either laser acupuncture or placebo laser. There was a significantly greater improvement in the treatment group than the controls for each time point. Symptoms of chronic tension-type headache abated significantly, and the effects were sustained through the follow up period of three months.

Acupuncture is a method of treatment rooted in an ancient Chinese culture that has existed for at least two millennia.<sup>18;22</sup> According to Chinese philosophy, acupuncture techniques are based on the hypothesis of meridians and energy flow. In the middle 1970s, the scientific basis of acupuncture analgesia began to be explored.<sup>23</sup> With growing support from scientific investigators, acupuncture in Western medicine has increasingly captured the interest of doctors and the general public and is now widely practised as an alternative therapy, mainly for pain relief.<sup>24</sup> Of the many clinical uses of acupuncture, acupuncture analgesia was one of the earliest aspects to be explained on the basis of Western physiology and anatomy, and is so far the most thoroughly researched.<sup>23</sup>

As the role of acupuncture in multidisciplinary clinics increases, the common but transient complications such as nausea and syncope, and the rare but occasionally fatal complications such as septicaemia, hepatitis and pneumothorax, cannot be entirely ignored.<sup>25;26</sup> The commonest alternative related techniques include the use of electric currents, particularly TENS, and low energy laser.<sup>19;20</sup> Laser acupuncture offers distinct advantages over traditional needling because the procedure is pain-free and non-traumatic. Its technique is easy to learn and there is no need for sophisticated instruments.<sup>19</sup>

Although the exact underlying neurophysiological mechanisms of acupuncture remain unclear, the results of human and animal studies suggest that acupuncture provides a neuro-modulating input into the central nervous system that can activate multiple analgesic or pain modulating systems involving neurotransmitters such as endogenous opioids.<sup>23</sup> In fact the most

frequently cited mechanism of action for the analgesic properties of acupuncture involves induction of endogenous opioid production and release.<sup>24;27</sup> In human subjects in whom pain was relieved by acupuncture, an increase in cerebrospinal fluid (CSF) endorphin level was noted.<sup>24</sup>

The general mechanism underlying the therapeutic effect of low energy laser is not fully understood, but King et al demonstrated that low energy Helium-Neon laser radiation on auricular acupuncture points elevates the pain threshold by raising the level of endorphins in the brain.<sup>28</sup> Since the acupuncture points of the ear can be regarded as powerful points commonly used in acupuncture, the efficacy of low energy Helium-Neon laser radiation might be regarded as providing compelling proof of the effectiveness of laser acupuncture. As for the intensity of the radiation used, the figures quoted in reference articles and literature vary, although higher radiation intensities have been popular.<sup>20;29</sup> Higher radiation intensity is more likely to stimulate target tissue and reduce the safety of the stimulation. As for the number and frequency of treatment sessions, a variety of arrangements has been proposed. However, the pattern used in our study, with 10 sessions at the rate of three per week, is common. To follow up the results of treatment of headache, a three-month follow up period of assessment may be sufficient according to previous studies.<sup>16;30</sup>

It is noteworthy that acupuncture can be effective in treating chronic pain, with success rates of between 55% and 85%.<sup>22</sup> The existing evidence suggests that acupuncture may have a role in the treatment of recurrent headaches.<sup>3</sup> There are trials with contradictory results, but the majority have concluded that acupuncture offers benefits in the treatment of headaches.<sup>31</sup> Since the mechanisms involved in laser acupuncture are not clearly understood, some workers do not include non-needling techniques into systematic reviews of acupuncture; however, those who use acupressure or laser acupuncture often hold the opinion that the crucial issue is the stimulation of the correct point, no matter by what means.<sup>32</sup>

Several concurrent pathophysiological mechanisms may be responsible for chronic tension headache. Evidence from various sources

suggests that tension headache is possibly associated with opioid system disturbance, and impairment of endorphin responsiveness could play a key role in headache susceptibility to environmental stimuli.<sup>33</sup> There is also evidence that patients with daily chronic headaches have lower than normal levels of plasma and CSF beta-endorphin.<sup>34,35</sup> Stimulation of acupuncture points can raise the endorphin level in the brain,<sup>22</sup> and can lead to an increase in activity of the opioidergic system, including panopioid activity and beta-endorphin levels in plasma.<sup>4</sup> However, some authors believe that the quality and amount of evidence is not fully convincing,<sup>3,36</sup> and there is evidence that beta-endorphin is not involved in the pathogenesis of chronic tension-type headache, or that such a role is not reflected in CSF or plasma concentrations of the neuropeptide.<sup>35</sup>

This study has limitations that could have affected the results. The study was performed 'subject blind', ie the patients were unaware of the treatment allocation. The acupuncturists administering the real or sham treatment and the assessors were aware of the allocation, and thus could have positively influenced the laser acupuncture group. The potential for bias was reduced, as far as possible, by using acupuncture naïve patients, and minimising the communication between the therapist and patient. The study could have been improved by using active and inactive laser devices that appeared identical, so that the acupuncturist did not know the group allocation. The evaluation was performed using a daily diary and questionnaires collated by an independent assessor and statistician. As the baseline measurements were made in a different way from follow up diaries, there may be some degree of measurement bias.

To our knowledge, this is the first randomised, placebo-controlled trial of laser acupuncture for chronic tension-type headache. A reasonable sample size and follow up period were employed, in comparison with some studies of acupuncture for headache. Both groups improved over the study period, but the patients receiving real laser acupuncture had a significantly greater improvement. Our results suggest that laser acupuncture may be an effective treatment for chronic tension-type headache, but deserves further research.

#### Summary points

Chronic tension-type headache is unresponsive to many treatments

There is some evidence that needle acupuncture has an effect

Low energy laser acupuncture has some practical advantages over needle acupuncture

This single blind RCT suggests that laser acupuncture has effects that justify further research

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