Laser Acupuncture for Migraine and Muscle Tension Headache: A Double-Blind Controlled Trial

Nicholas G Lavies

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Summary
Twelve patients with chronic migraine recruited from a neurology clinic or a self-help group were randomly allocated to receive either 6 weeks active laser acupuncture or 6 weeks dummy laser acupuncture. Patients completed headache diaries for the 6 weeks prior to treatment and for 6 weeks following. They were then crossed over to receive the alternative treatment for a further 6 weeks. Neither patients nor operator knew which unit was the active one. There was a reduction in mean total headache score (combining duration and severity) of 18% in the active group and 43% in the control group following the first treatment period. This difference was not significant. Following the second treatment period, mean scores increased by 50% in the active group and 5% in the control group but again this difference was not significant due to inconsistent responses by some patients. When active and placebo treatments were computed for all patients, there were still no significant differences. It is concluded that laser acupuncture does not have an important clinical effect in migraine over and above the expected placebo response.

Key words
Acupuncture, Headache, Low-power laser, Migraine, Randomised placebo-controlled crossover trial.

Introduction
Headache (both migrainous and muscle tension) is a condition commonly treated with acupuncture in pain clinics. Results from uncontrolled studies have shown moderate to marked improvement in 54% to 92% of patients (1,2). However, most of the controlled trials are difficult to evaluate because of deficiencies in assessment criteria and the use of different forms of treatment as placebo, e.g. mock or sham acupuncture (3). Only one adequate controlled trial of acupuncture in migraine has been reported in which no significant difference was found between acupuncture and control groups, although the expected placebo response was observed (4).

Laser acupuncture is a relatively new development which involves the stimulation of acupuncture points by low-power laser, and reports from the USA and West Germany have suggested beneficial effects on wound healing and arthritis (5,6). It had been believed to work in the same way as traditional acupuncture but without the discomfort to the patient; however there is now evidence that there is release of neither endogenous opioids nor serotonin, thus it is unlikely that any analgesic effect of laser stimulation is through the same mechanism as acupuncture (7). Indeed, controlled trials now suggest that laser has little if any analgesic action on most forms of musculo-skeletal pain (8). It is probable that the effect of bright light, be it laser or non-coherent natural light (9), is to enhance healing, and thus provide a reduction in pain through anti-inflammatory action and an accelerating effect on tissue repair.

Since the patient does not usually experience any sensation with laser stimulation, and its application does not require any special training, it is possible to design a true double-blind controlled trial, something that has so far eluded researchers in acupuncture (10). I set out to perform such a study in migraine sufferers.

Method
The study was approved by the District Ethics Committee. Twelve Patients were recruited from either a neurology clinic or the local migraine self-help group. Most suffered from both migraine and muscle tension headaches of many years duration and had tried a variety of medication without long-lasting benefit. They were instructed to carry on taking whatever medication they had been prescribed in order that the acupuncture was the only change in treatment. Two patients were taking clonidine and one pizotifen. The minimum entry criterion was at least two migraines per month.

Each patient was randomly allocated by the toss of a coin into one of two groups. Group 1 received active laser acupuncture first and dummy laser acupuncture second, with group 2 vice versa. Each treatment period consisted of 6 treatments, one a week for six weeks, with the laser (Alfa laser) during which traditional Chinese acupuncture points were
stimulated bilaterally for 40 seconds at each point. Points used were: LR.3, ST.36, LI.4, GB.20. The dummy laser unit was identical to the active unit, but the suppliers had disconnected the power supply to the probe internally. The units had different serial numbers, but neither the patients nor the operator (NCL) knew which was the active unit, thus the procedure was truly double-blind.

Assessment was made by means of a headache diary. Patients completed a diary for six weeks prior to starting treatment and for six weeks afterwards. Headaches were graded on a simple three point severity scale and their duration noted to the nearest hour. A total headache score was then computed for each assessment period by multiplying the severity score by the duration in hours for each headache and then adding all these figures together. The number of days in each six week period that a headache was documented was also noted and expressed as total headache days.

The second course of treatment followed on immediately after the second assessment period, thus making a total time span of 30 weeks for each patient. Statistical analysis was by paired and unpaired t tests as appropriate. P values less than 0.05 were considered significant.

Results
No attempt was made to separate migraine from non-migrainous headaches, since acupuncture is known to be effective for both and patients often cannot clearly differentiate between them (11). Details of the first treatment period are given in Tables 1 and 2. There was an overall improvement in both groups after the first course of treatment, which was significant in group 1. However, the percentage change was not significantly different between the groups, either in total headache score or in total headache days.

Comparison of the initial total headache score with the final total headache score for all patients revealed little difference, with an average change for all patients of -6%. Three patients were more than 50% better off, and three patients were more than 50% worse off, with the remainder within these limits.

Discussion
Lasers were first introduced into medical practice in the late 1960s in the USA and USSR. The photobiological effects of low-power lasers have been described mainly from the USSR, and remarkable therapeutic success has been claimed for the treatment of leg ulcers, burns and radiodermatitis (12). Lasers in the red and infra-red wave bands are most useful because they penetrate more deeply without causing tissue destruction (6).

By contrast, there was an overall deterioration in both groups following the second course of treatment. Details are given in Tables 3 and 4. Again there was no significant difference in the percentage change between the two groups.

Figures 1 and 2 depict the percentage change in each patient from the baseline, zero, to second assessment period and to third assessment period. It can be seen clearly that the general trend in both groups is for improvement at first followed by deterioration. When both groups were combined, the difference between the mean percentage change for the first treatment (-24%) and that for the second treatment (+89%) just failed to achieve statistical significance (P=0.06).

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### Table 1
**FIRST TREATMENT:**
**MEAN TOTAL HEADACHE SCORE (+SEM)**

<table>
<thead>
<tr>
<th>Pre</th>
<th>Post</th>
<th>Change</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Active)</td>
<td>531±239</td>
<td>435±236</td>
<td>-18%</td>
</tr>
<tr>
<td>Group 2 (Placebo)</td>
<td>176±89</td>
<td>101±54</td>
<td>-43%</td>
</tr>
</tbody>
</table>

P is for % Change Group 1 vs Group 2
NS = not significant

### Table 2
**FIRST TREATMENT:**
**MEAN TOTAL HEADACHE DAYS (+SEM)**

<table>
<thead>
<tr>
<th>Pre</th>
<th>Post</th>
<th>Change</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Active)</td>
<td>22±6.2</td>
<td>18±6.0</td>
<td>-18%</td>
</tr>
<tr>
<td>Group 2 (Placebo)</td>
<td>12±4.1</td>
<td>6±2.3</td>
<td>-50%</td>
</tr>
</tbody>
</table>

P is for % Change Group 1 vs Group 2
NS = not significant

### Table 3
**SECOND TREATMENT:**
**MEAN TOTAL HEADACHE SCORE (+SEM)**

<table>
<thead>
<tr>
<th>Pre</th>
<th>Post</th>
<th>Change</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Placebo)</td>
<td>435±236</td>
<td>457±167</td>
<td>+5%</td>
</tr>
<tr>
<td>Group 2 (Active)</td>
<td>101±54</td>
<td>150±84</td>
<td>+50%</td>
</tr>
</tbody>
</table>

P is for % Change Group 1 vs Group 2
NS = not significant

### Table 4
**SECOND TREATMENT:**
**MEAN TOTAL HEADACHE DAYS (+SEM)**

<table>
<thead>
<tr>
<th>Pre</th>
<th>Post</th>
<th>Change</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (Placebo)</td>
<td>18±6.0</td>
<td>20±6.5</td>
<td>+11%</td>
</tr>
<tr>
<td>Group 2 (Active)</td>
<td>6±2.3</td>
<td>10±3.8</td>
<td>+67%</td>
</tr>
</tbody>
</table>

P is for % Change Group 1 vs Group 2
NS = not significant
phospholipid of the cell membrane and may also affect the metabolism of inflammatory mediators (13).

I chose to study a condition which often benefits from traditional acupuncture, although the published literature does not support this conclusively (13). The cross-over design was chosen in an effort to increase the power of the study using a relatively small number of patients acting as their own controls. The other perceived benefit was that all patients knew they would receive the active laser at some stage and were therefore less likely to drop out. However, cross-over designs have their own drawbacks (14), in particular: there is no certainty that treatment given in the first period does not have a carry-over effect in the second. A longer wash-out time between interventions might have provided a greater safeguard against this, and therefore improved validity of the study.

One of the main problems in studying headache is the episodic nature of the attacks. The entry criterion was at least 2 migraine attacks per month, rather less than used by Dowson et al. (4), but in fact the number of days on which headache was reported was far in excess of this (a mean of 22 days for group 1 and 12 days for group 2). Thus although 6 weeks is a relatively short assessment period, using total headache days gives a number more amenable to statistical analysis than number of attacks and is also clinically more relevant to the patient.

The other score used for analysis was total headache score, which combined both duration and severity of headache. If the treatment were to influence the severity rather than the number of attacks then it should show up using this score.

Other researchers have used patients' own reports of improvement (11), but I found this to be highly unreliable and to have no correlation with what the patients wrote in their diaries. I have not, therefore, included this data in the analysis.

Most patients improved following both active and placebo laser. If Melzack's definition of successful pain relief (at least 33% benefit) is applied, then two from group 1 and four from group 2 achieved success. This is more than the expected 35% placebo response, but headache sufferers are well-known to be strong placebo responders (4).

The finding of no significant difference between the two groups can be interpreted in two ways: either laser has no therapeutic effect above that of a placebo, or it does but this study has not had sufficient power to detect a difference (i.e. a Type II error). The second treatment period strictly does not constitute a valid cross-over since a continuing effect from the first treatment cannot be discounted. Nevertheless, when the active laser treatment period is analysed for all patients, the result is the same, i.e. no significant difference from the placebo group.

Conclusion

I conclude, therefore, that laser acupuncture as carried out in this study does not have an important clinical effect in headache. A minor effect is not ruled out, although a much larger number of patients would be required to show this.

Acknowledgements

I would like to thank David White of Voltastar Ltd for kindly arranging the loan of two Affalaser Units for the duration of the study. I would also like to thank Edna Smith of the Migraine Trust for her help in recruiting individuals for the study, and all the migraine sufferers who took part.

Note

The clinical work for this article was performed in 1990 at Leicester Royal Infirmary. Unfortunately some technical details relating to the method of treatment have now been lost, in particular the power output (thought to have been 10mW) and the pulse frequency.

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References


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