Relief of chronic neck and shoulder pain by manual acupuncture to tender points—a sham-controlled randomized trial

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SUMMARY. Objectives: To compare the effects of real acupuncture to tender points for neck and shoulder pain and stiffness (Japanese: katakori) with those of sham acupuncture. Design: Randomized-controlled trial. Methods: Thirty-four volunteers from an acupuncture school with complaints of chronic pain and stiffness, who had no arm symptoms and gave informed consent, were randomly allocated to acupuncture or sham groups. Acupuncture or sham acupuncture was applied to the tender points once a week for 3 weeks. In the acupuncture group the acupuncture needle was inserted to the muscle, then the sparrow pecking technique was applied five times. Sham acupuncture was done without insertion of the needle. Dull pain and stiffness were evaluated by visual analog scale (VAS) before, and every 2 days after the first needling for 1 month. Pressure pain threshold on the tender points was measured before and after each treatment. Results: There was no statistical difference of VAS scores between acupuncture and sham groups 9 days after the last treatment. However, the acupuncture group showed significant reduction of VAS scores immediately after and/or 1 day after the real acupuncture treatments (P < 0.01). The effect tended to be prolonged after repeated treatment. Pressure pain thresholds tended to increase after real acupuncture treatment but not after sham acupuncture. Conclusions: Acupuncture applied to tender points appears to have short-term effects on neck and shoulder pain and stiffness, but this study was unable to demonstrate any long-term superiority over sham acupuncture. © 2002 Elsevier Science Ltd. All rights reserved.

INTRODUCTION

Chronic dull pain and stiffness of the neck and shoulder are very common symptoms. Acupuncture treatment has been used for pain relief for a long time. Several studies have examined the efficacy of acupuncture treatment for such conditions, however, the results are mixed. Positive results were obtained in studies that used nonacupuncture control groups,1–4 and negative results tended to be reported in those that used sham acupuncture or mock transcutaneous electrical nerve stimulation (TENS).5,6 It is possible that insufficient sample size and problems with the choice of the control (sham) might be the major causes of such discrepancies. The importance of the sham-controlled randomized-controlled trial (RCT) in acupuncture is that it excludes strong placebo effects and clarifies the specific effects of acupuncture. Minimal acupuncture, 

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a shallow and weak needling technique, has been proposed as a sham technique, but this procedure is a form of acupuncture practiced in Japan, and our previous study suggested that shallow and weak needling has analgesic effects. For the purpose of pain relief, the choice of nonacupuncture points as a sham treatment is also a problem because of the existence of diffuse noxious inhibitory controls (DNIC) phenomena; it is well established that painful stimulation inhibits pain, and DNIC has been proposed as a physiological basis of acupuncture analgesia. We conducted a sham-controlled RCT to evaluate the effectiveness of real acupuncture to tender points as a treatment for chronic dull pain and stiffness of the neck and shoulder (Japanese: katakori). For sham control, blunt acupuncture needles were used. The subjects’ assessment of the blinding procedure was also evaluated.

METHODS

Patients

Patients were recruited from the students of an acupuncture school in Japan who complained of chronic dull pain and stiffness of the neck and shoulder without any arm symptoms. Thirty-four subjects who gave written informed consent were enrolled and randomly allocated to acupuncture group (AG) or sham group (SG) by use of a computerized randomization program. Ethical approval for this protocol was given by the ethics committee of Meiji School of Oriental Medicine.

Intervention

Five well-trained licensed acupuncture instructors performed the acupuncture. They had been specially trained for the procedures of searching thoroughly for the tender points and the sham acupuncture technique. They were asked to maintain the same attitude to both groups (AG and SG) to avoid psychological influences.

In AG, disposable stainless needles (0.2 mm × 40 mm, Seirin Co. Ltd.) were inserted into the muscle, to a depth of about 20 mm, and the ‘sparrow pecking’ technique (alternate pushing and pulling of the needle five times) was applied. When the subject felt a kind of dull pain or acupuncture sensation (de qi), the manipulation was stopped and the needle retained for five more minutes. For sham acupuncture, similar stainless needles (0.2 mm × 40 mm) were used, but the tips had previously been cut off to prevent the needle penetrating the skin. The cut ends were smoothed with sandpaper manually under clean conditions. The acupuncturist pretended to insert the needle and to use the sparrow pecking technique, then removed the needles. A simulation of needle extraction was performed after 5 min, by touching the patient and noisily dropping needles into a metal case. All tender points were carefully detected where the subjects felt dull pain and stiffness (neck, shoulder, and back) and were used for the acupuncture treatment. All tender points were treated in each group. In both groups, the subjects received three treatments at weekly intervals.

Evaluation

The subjective magnitude of pain and stiffness (katakori) was rated by visual analog scale (VAS) at each of three sites (neck, shoulder, and back) and overall. The pain intensities were assessed on the 6th, 4th, and 2nd days before the start of treatment; just before and immediately after each treatment; and on the 1st, 3rd, and 5th day after each of the three treatments. Measurements were also done on the 7th and 9th day after the final treatment. Pressure pain thresholds (PPTs) were measured by the acupuncturist using a pressure algometer (Yufu-Seiki, F P Meter, with probe of 10 mm) just before and immediately after each treatment. The PPT was measured three times in each point, the median values were used for statistical analysis.

Assessment of the blinding technique

To examine the efficacy of the blinding technique of this study, the subjects were asked to select an answer for the question “How did you feel when the acupuncture needle was inserted?” at the end of this trial. The available answers were: (1) needles were inserted into the muscle, (2) needles did not penetrate the skin; and (3) I could not discriminate the difference.

Statistical analysis

Unpaired t-tests were used for the primary measure, a between-group comparison of overall VAS scores on the 9th day after the third treatment. Dunnett’s test was used for within-group comparisons. Changes in PPTs were analyzed by paired t-test. The assessment of the blinding procedure was analyzed by chi-square test. Missing data were replaced with the mean of all patients’ scores and included in the intention-to-treat analysis. Stat View for Macintosh (ver. 4.5) was used for the statistical analysis.

RESULTS

Thirty-four subjects (age range 20–63 years) were enrolled. There were 5 male and 12 female (mean age 34.2 ± 10.8 years) in AG, and 5 male and 12 female (mean age 30.8 ± 12.0) in SG. Two subjects in AG and five subjects in SG missed the third treatment as a result of traffic delays due to bad weather. Adverse effects were not the cause of drop out in this study.
Manual acupuncture to tender points for chronic neck and shoulder pain relief

Fig. 1 Number of tender points located at various sites during three examinations, within 5 cm of the most common region, in acupuncture (A) and sham (B) groups.

Distribution of the tender points

The tender points detected in neck, shoulder, and back of both subjects in AG and SG are shown in Figure 1. The distribution of the tender points is similar between the two groups. The tender points were located close to traditional acupuncture points such as BL-10, GB-20, GB-12, GL-21, and BL-43. There are no statistically significant differences of mean number of the tender points (treatment points per subject) between AG (mean of 6.5 ± 2.3 points, range 2–12) and SG (mean of 6.7 ± 2.3 points, range 2–12).

Table 1 Summary of overall VAS scores in acupuncture (AG) and sham (SG) groups (mean ± S.D.)

<table>
<thead>
<tr>
<th></th>
<th>Just before the first treatment</th>
<th>9 days after third treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole</td>
<td>AG 52.8 ± 25.5</td>
<td>44.1 ± 20.1</td>
</tr>
<tr>
<td></td>
<td>SG 51.9 ± 22.5</td>
<td>49.7 ± 23.3</td>
</tr>
<tr>
<td>Neck</td>
<td>AG 60.5 ± 15.0</td>
<td>43.3 ± 19.7</td>
</tr>
<tr>
<td></td>
<td>SG 48.8 ± 27.9</td>
<td>46.8 ± 25.4</td>
</tr>
<tr>
<td>Shoulder</td>
<td>AG 54.2 ± 21.8</td>
<td>44.4 ± 21.3</td>
</tr>
<tr>
<td></td>
<td>SG 50.1 ± 22.9</td>
<td>52.9 ± 24.3</td>
</tr>
<tr>
<td>Back</td>
<td>AG 46.8 ± 20.9</td>
<td>36.6 ± 18.3</td>
</tr>
<tr>
<td></td>
<td>SG 46.6 ± 18.5</td>
<td>37.6 ± 20.9</td>
</tr>
</tbody>
</table>

The VAS scores tended to decrease after the acupuncture treatments. Table 1 summarizes the effects of real and sham acupuncture on overall VAS scores. There was no statistical difference between AG and SG in VAS scores just before the first treatment or on 9th day after the third treatment (unpaired t-test). As shown in Figure 2, the mean VAS scores tended to decrease.
Table 2 Pressure pain threshold (PPT) measured before and immediately after three treatments with acupuncture (AG) or sham (SG)

<table>
<thead>
<tr>
<th></th>
<th>n1</th>
<th>n2</th>
<th>n3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AG</td>
<td>27</td>
<td>1.7 ± 0.7</td>
<td>2.1 ± 0.9**</td>
</tr>
<tr>
<td>SG</td>
<td>26</td>
<td>1.6 ± 0.9</td>
<td>1.6 ± 1.0</td>
</tr>
<tr>
<td>Shoulder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AG</td>
<td>45</td>
<td>2.4 ± 1.8</td>
<td>2.9 ± 2.3**</td>
</tr>
<tr>
<td>SG</td>
<td>44</td>
<td>2.0 ± 1.4</td>
<td>2.1 ± 1.3</td>
</tr>
<tr>
<td>Back</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AG</td>
<td>24</td>
<td>2.3 ± 0.8</td>
<td>2.7 ± 1.1**</td>
</tr>
<tr>
<td>SG</td>
<td>27</td>
<td>1.9 ± 1.0</td>
<td>2.1 ± 1.0**</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD.
*P < 0.05.
**P < 0.001, paired t-test, before vs. after.

DISCUSSION

In the present sham-controlled RCT, there was no overall statistically significant difference between the real and sham acupuncture to the tender points, 9 days after the third treatment. However, real acupuncture produced statistically significant short-term improvements. The assessment of the blinding procedure indicated that the subjects could not discriminate sham from real acupuncture.

Effects of real or sham acupuncture on chronic neck and shoulder pain

The present findings suggest that subjective pain and VAS scores decrease immediately after real acupuncture treatment to the tender points, and these effects tended to be augmented by repeating treatment to a total of three times. On the other hand, the sham procedure was associated with inconsistent effects.

In this study, we used tender points as the treatment sites. The number of the points treated was not fixed but depended on the number of tender points detectable in each subject. The mean number of tender points treated was six. These results also suggest the importance of treatment frequency since a reduction of VAS scores was not sustained for a week. Treatment more than once per week might be more effective.

Effectiveness of the tender point as a treatment site for acupuncture

Tender points were used in this study instead of traditional acupuncture points. Tender points are a category of acupuncture point, the Ah Shee or ‘oh-yes point,’ and have been used as treatment. Our survey of well-trained Japanese acupuncturists demonstrated that they often choose tender points as treatment sites. Melzack et al. pointed out that the location of acupuncture points was in agreement...
with that of the trigger points in 71% of examples tested.\textsuperscript{13} On the other hand, the number of points that are tender out of 18 specified sites is employed as a criterion of patients with fibromyalgia by the American College of Rheumatology (ACR).\textsuperscript{14} The sites they specify are very close to those of the traditional acupuncture points.

In this study, the tender points found tended to be located near to acupuncture points. The close proximity of tender points and traditional acupuncture points leads us to suggest that the tender points may be a primitive form of acupuncture points, and that they have been systematically arranged into the traditional acupuncture points.

The clinical relevance of tender points and/or trigger points has long been suggested.\textsuperscript{15} There are few sham-controlled RCTs of tender point acupuncture. The efficacy of using tender points as the treatment site is also supported by physiological evidence from deep pain measurement.\textsuperscript{16} Tender points are supposed to be the sites where the nociceptors, polymodal-type receptors, have been sensitized by various factors. The polymodal-type receptors are also proposed as a possible candidate for acupuncture and moxibustion with selective stimulation of the polymodal receptors by chemical, thermal, and mechanical stimulation producing analgesic effects.\textsuperscript{17} These data suggest that acupuncture stimulation of the tender points may activate sensitized polymodal-type receptors more powerfully, resulting in stronger effects on pain relief.

**Sham acupuncture technique**

The importance of the sham-controlled RCT to control for the strong placebo effects of acupuncture has been debated.\textsuperscript{18} There are many RCTs of acupuncture in which various control groups have been employed, such as no-treatment controls,\textsuperscript{3,19,20} mere pricking (without penetration),\textsuperscript{5,21,22} minimum acupuncture (shallow and week needling),\textsuperscript{23} mock TENS (without current pulse),\textsuperscript{2,6,24–26} and so on.\textsuperscript{27–29}

The sham acupuncture technique used in this study was very simple. We used a needle that had previously had its tip cut off so that it was blunt. The practitioner applied the same procedures as with the real acupuncture. Blinding in this study appears to have been successful. About half the subjects in SG answered that they had received real acupuncture in the muscle despite the subjects being students of a Japanese acupuncture school where they have had much experience of acupuncture needle insertion. One of the reasons for this success of the blinding technique could be that the tender points we used were limited to the back of the neck, shoulder, and back and the subjects could not see the site of needle insertion. It is likely that this sham acupuncture technique cannot be applied to other needling sites such as the arms and legs.

Recently, Streitberger and Kleinhenz\textsuperscript{27} and Kleinhenz et al.\textsuperscript{28} developed a unique sham acupuncture technique. The shaft of the needle is not fixed to the handle and it is held by a covered plastic ring. When the sham needle appears to be inserted, the handle moves towards the skin while the shaft of the needle retracts into the handle. This gives the appearance of needle insertion. Although there are several problems with this sham acupuncture technique,\textsuperscript{29} it is worth examining its usefulness for future RCTs of acupuncture.

**Volunteer bias in this study**

A significant limitation of this study was that the subjects were students of an acupuncture school. They have considerable experience with acupuncture treatment and the specific sensation of de qi, and they are also confident in acupuncture. It has been found that previous experience with acupuncture and confidence in the efficacy of acupuncture influences the effect of acupuncture.\textsuperscript{5} Thus, the effects of acupuncture treatment in both groups were probably augmented by volunteer bias, to some extent.

**ACKNOWLEDGEMENTS**

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**REFERENCES**


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