Relief of low back pain immediately after acupuncture treatment – a randomised, placebo controlled trial

Motohiro Inoue, Hiroshi Kitakoji, Naoto Ishizaki, Munenori Tawa, Tadashi Yano, Yasukazu Katsumi, Kenji Kawakita

Abstract
Background The purpose of this study was to examine the immediate effect of single acupuncture stimulation to the most painful point in patients with low back pain.

Method A randomised, evaluator-blinded, sham controlled clinical trial was conducted in which 31 patients with low back pain were randomly allocated to either an acupuncture group (n=15) or a sham acupuncture group (n=16). Both acupuncture and sham acupuncture were performed at the most painful point on the lower back of the subjects. For the acupuncture group, a stainless steel needle was inserted to a depth of 20mm and manually stimulated (sparrow pecking method) for 20 seconds, while for the sham treatment a guide tube without a needle was placed at the point and tapped on the skin. Changes in low back pain were evaluated with a visual analogue scale (VAS) and the Schober test. Participants were also asked if they felt the needling sensation or not. The therapy and the evaluation were independently performed by two different acupuncturists.

Results VAS score and the Schober test score showed significant improvement after treatment as compared with the sham group (P=0.02, 0.001, respectively). There were no significant differences in the needling sensation between the acupuncture and sham group.

Conclusion These results suggest that acupuncture at the most painful point gives immediate relief of low back pain.

Keywords Randomised control trial, low back pain, acupuncture, sham acupuncture.

Introduction
Acupuncture seems to be a clinically effective treatment for acute and chronic pain, and a considerable amount of research is being conducted on its role in suppressing pain. One particular area of research is low back pain, and many studies seem to show that acupuncture is not superior to sham acupuncture, though a recent review was more promising.

In order to clearly demonstrate the usefulness of the treatment for low back pain, it is necessary to establish both its immediate and long term effects in clinical trials. Our clinical experience suggests that if acupuncture can achieve an immediate effect, then it can be repeated to achieve a permanent improvement of the symptoms. Therefore, we argue that it is important to demonstrate an immediate improvement in comparison with a control group.

In this trial, our aim was to compare the immediate effect of acupuncture treatment at the most painful point, compared with sham acupuncture, for low back pain.

Method
This trial was conducted from April 2003 to December 2004 in patients who had received a consultation for low back pain at the Acupuncture and Moxibustion Centre attached to Meiji University of Oriental Medicine. Participants included both those newly referred and those re-attending. Participants were included after giving informed consent, if they presented with only low back pain in a limited area, which was exacerbated in particular postures (flexion, extension, lateral bending and...
rotation of the lumbar region, or any combination of these movements). Therefore, patients with leg symptoms, patients unable to accurately locate the area of pain, and patients whose pain was not worsened by changes in posture were excluded. We wished to concentrate on pain in a limited area in this study. All patients were examined by an orthopaedic surgeon prior to enrolment, and any whose symptoms or findings on imaging indicated the need for medication or surgery or suggested an underlying disease were excluded. All subjects had previous experience of acupuncture.

Acupuncture and sham acupuncture, and the evaluations of pre- and post-acupuncture and sham acupuncture were conducted by different acupuncturists, and all evaluation acupuncturists were blinded to the patient’s group allocation. This was a subject- and evaluator-blind study. All patients were randomly allocated to two groups using random selection software (Sample Size 2.0, Blackwell Science Ltd.), concealed from patients and evaluators.

A total of 31 patients participated in the trial, with 15 in the acupuncture group and 16 in the sham acupuncture group. All the participants completed the study. The trial was conducted in observance of the Helsinki declaration and with the approval of the ethics committee of the Meiji University of Oriental Medicine.

**Intervention**

In the acupuncture group, the therapists inserted a stainless steel needle (40mm in length and 0.18mm in diameter, Seirin Co. Shizuoka, Japan) to a depth of 20mm at the most painful point and stimulated the needle with the sparrow pecking method (lifting and thrusting) for 20 seconds. In the sham group, the therapists tapped the end of a guide tube on the skin at the most painful point, without a needle, and then acted as if they were inserting a needle there according to the method reported by Nabeta et al.13 The patients were informed they would receive one of two types of acupuncture treatment, without mentioning the word sham.

**Evaluation**

Before the intervention, the standing patients were instructed to adopt the posture that produced the worst pain, then indicate the location of the pain (without pressing on the area), then score the severity of the pain on a 100mm visual analogue scale (VAS) with the right end indicating maximum pain and the left end absolutely no pain. Evaluators marked the point and reported it to the acupuncturist by indicating the location with their index finger. They also confirmed that the posture was identical at before and after the treatment.

Next, the range of lumbar spinal flexion was measured with the Schober test, which was developed for diagnosing ankylosing spondylitis.12 With the patient erect, the position of the second median sacral crest was identified, and marks made 50mm below and 100mm above this point. Patients were then instructed to bend forward as much as possible, and the distance between the two marks was measured. All the evaluators were licensed acupuncturists with substantial clinical experience and trained in clinical examination.

Immediately after treatment, patients were asked to score the VAS while adopting the most painful posture as before, after which the Schober test was performed again. Following the intervention, each patient was asked whether he or she felt a needling sensation or not, to confirm their awareness of needle insertion.

**Statistical Analysis**

Within-group changes in VAS score and the Schober test score were tested by paired two sample t tests. The difference in the ratios of the subjects in the two groups aware and unaware of needle insertion was tested by Fisher’s Exact Test. The changes in the VAS and Schober test scores after treatment in both groups, and the interaction with those and awareness of the needling sensation were evaluated by two-way ANOVA. All analyses were computed with Statview Version 4.5 (Sas Institute Japan). Results were considered significant when the P value was less than 0.05.

**Results**

Thirty one patients who complained of low back pain were all diagnosed with lumbar vertebral arthritis by a physician, according to radiological or MRI findings. Tables 1 and 2 show the characteristics of the subjects, and no important differences were found between the groups at baseline.

Changes in VAS scores after the intervention are shown in Table 2. Both groups showed a significant within-group change (P<0.001 for acupuncture group,
P=0.033 for sham group), but the reduction was larger in the acupuncture group than the sham group (F(df,ν)=8.412, P=0.007). Furthermore, the degree of decrease in the VAS score after treatment showed a significant difference between the two groups (P=0.020) as shown in Figure 1. The changes in the Schober test score in each group are shown in Table 2. The within-group change

### Table 1: Characteristics of participants

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
<th>Sex</th>
<th>Age in years mean ± SD</th>
<th>Duration of back pain in months mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture</td>
<td>15</td>
<td>male=11</td>
<td>61±6</td>
<td>83±59</td>
</tr>
<tr>
<td>Sham acupuncture</td>
<td>16</td>
<td>male=10</td>
<td>70±5</td>
<td>84±6</td>
</tr>
</tbody>
</table>

### Table 2: Changes in VAS and Schober test score after interventions, and in subgroups according to needling sensation

<table>
<thead>
<tr>
<th>Treatment</th>
<th>VAS (mean ± SD, mm)</th>
<th>Schober test (mean ± SD, mm)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment</td>
<td>After treatment</td>
<td>Difference</td>
</tr>
<tr>
<td>Acupuncture total (n=15)</td>
<td>61±11</td>
<td>47±7</td>
<td>-15±9</td>
</tr>
<tr>
<td>Felt needling sensation (n=9)</td>
<td>65±10</td>
<td>47±6</td>
<td>-18±8</td>
</tr>
<tr>
<td>No needling sensation (n=6)</td>
<td>55±12</td>
<td>45±10</td>
<td>-10±7</td>
</tr>
<tr>
<td>Sham acupuncture total (n=16)</td>
<td>61±9</td>
<td>55±13</td>
<td>-5±9</td>
</tr>
<tr>
<td>Felt needling sensation (n=6)</td>
<td>64±9</td>
<td>56±13</td>
<td>-8±13</td>
</tr>
<tr>
<td>No needling sensation (n=10)</td>
<td>59±9</td>
<td>55±14</td>
<td>-4±6</td>
</tr>
</tbody>
</table>

Figure 1: The changes in VAS scores after intervention are shown for the two groups, together with mean and SD.
was statistically significant in the acupuncture group (P<0.001), but not in the sham group (P=0.414). The between-group change showed a significant difference between the two groups (P<0.001), as seen in Figure 2.

There was no significant difference in the decrease in VAS scores (Figure 3) or Schober test scores (Figure 4) in the subgroups who reported being aware or unaware of needle insertion (VAS score P=0.071, Schober test score P=0.640). There also was no
interaction between changes in VAS and awareness of the needling sensation (F(1, 27) = 0.473, P = 0.498), Schober test score (F(1, 27) = 0.028, P = 0.868).

Discussion

With the onset of low back pain, many patients in Japan receive their first consultation from an orthopaedic surgeon. In general, during the acute stage orthopaedic surgeons prescribe rest as a fundamental treatment, together with oral and topical pharmaceuticals, followed by rehabilitation including physiotherapy during the sub-acute and chronic stages. For cases in which radiculopathy is so severe that it is not alleviated by conservative treatment, operative treatment may be performed, depending on the pathology. Very few patients experiencing low back pain for the first time select acupuncture as their first treatment, but only when conservative measures have not alleviated the pain, and when the symptoms do not warrant surgery. Clinical experience has shown that acupuncture is effective for many of these patients, and that they wish to have it again when their pain relapses presumably because they were satisfied with it. Thus, it seems likely that acupuncture is an effective treatment for mild to moderate low back pain that does not require surgery, even though numerous controlled clinical trials have yet to prove the effect.8-10;14

There are many acupuncture methods for treating low back pain, but using a simple approach, we gave acupuncture at the single location where patients felt the most pain, and compared the immediate effect against sham acupuncture. There was no significant difference in the number of patients in the two groups who reported that they had felt the needle being pushed in, which we take to mean that the control was a successful sham.

Although the VAS score showed a significant improvement both in the acupuncture and the sham group, greater improvement was obtained by acupuncture needling. Change in the Schober test score showed significant improvement after acupuncture treatment, while there was no significant change in the sham group. Furthermore, the degree of change in the score in the acupuncture group was significantly greater than that in the sham group. The results of this study show that needling at the most painful point on the lower back clearly has an immediate effect to improve low back pain and improve flexibility of the lumbar spine. Some mechanisms such as descending inhibition by CNS or activation of inhibition in the spinal cord may be involved in pain relief.15;16
There is no interaction between the degree of change in the VAS or Schober test score and awareness of the needling sensation, indicating that the needling sensation may not be necessary to obtain an effect with acupuncture. However, in the acupuncture group, there appears to be a trend towards greater improvement on VAS scores with needling sensation, as shown in Figure 3, suggesting that the difference might become significant with larger sample size.

We consider that an immediate response in controlling pain is important, and could point to the possibility of long term improvement with repeated treatment. However, the relevance of our study is limited because clearly long-term improvement is the relevant clinical outcome, and acupuncture given at the single most painful location is rare.

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Reference list

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