

Comparison of the effectiveness of acupuncture treatment and local anaesthetic injection for low back pain: a randomised controlled clinical trial

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ABSTRACT

Objective: To compare the effectiveness of repeated acupuncture stimulation and local anaesthetic injection at the most painful points in patients with low back pain.

Method: This randomised controlled clinical trial involved 26 patients with low back pain randomly allocated to either an acupuncture group (n = 13) or a local anaesthetic injection group (n = 13). Both acupuncture and anaesthetic injection were performed at two to five of the most painful points on the lower back once weekly for 4 weeks. In the acupuncture group, a 0.18 mm diameter stainless steel needle was inserted to a depth of 10–20 mm and manual stimulation was applied. In the local anaesthetic injection group, a 0.5 mm diameter needle was inserted to a depth of 10–20 mm and a local anaesthetic was injected. Participants evaluated pain using a Visual Analogue Scale immediately before and after the first treatment, before each subsequent treatment, and at 2 weeks and 4 weeks after completion of treatment.

Results: There was a significant difference between the two groups in the change in Visual Analogue Scale pain scores (p<0.01), with acupuncture providing more favourable results than local anaesthetic injection. The reduction in pain score from baseline calculated at each time period was significantly different between the two groups after the first (p<0.05) and final (p<0.01) treatments, and during the follow-up period (after 2 weeks (p<0.01) and 4 weeks (p<0.05)).

Conclusion: Both injection and acupuncture relieved pain, but acupuncture was superior for the immediate and sustained effects, suggesting that it is a useful treatment for low back pain. The difference in the effects may be attributable to differences in the mechanism of pain suppression.

Numerous comparative trials have been conducted to evaluate the effectiveness of acupuncture for treating low back pain.^{1–8} However, some of them suggested a possibility that acupuncture involves placebo effect^{5–7} and results from a meta-analysis indicated that acupuncture failed to show superiority over sham procedure in terms of reducing pain in the low back.⁹ Injection therapy is one of the treatments for patients with low back pain with respect to its effectiveness for short-term and long-term pain relief. It is given into the facet joints, the epidural space, the spinal nerve root, the intervertebral disc, the lumbar sympathetic chain, sacro-iliac joints and also into local ligaments, muscles or trigger points¹⁰ with the pharmacological agent such as corticosteroids,^{11–12} anaesthetics^{13–14} or other agents including non steroidal

anti-inflammatory drugs,¹⁵ sodium hyaluronate,¹⁶ sarapin,¹⁷ morphine¹⁸ and Vitamin B₁₂.¹⁹ However, the effectiveness of injection therapy for low back pain is not satisfactorily investigated.^{20–21} According to previous reports and our experiments, a possibility arises that acupuncture might be comparable or even superior to the effect of injection therapy for the treatment of low back pain. Herein we investigated the effect of acupuncture at the local point with maximal tenderness in the patients with low back pain, comparing the effect with the local anaesthetic injection at the same points.

METHODS

The trial was conducted from April 2005 to December 2006 with 26 patients who presented with low back pain at the Department of Orthopedic Surgery, Meiji University of Integrative Medicine. Written informed consent was obtained from all the participants in the trial, none of whom had prior experience of local anaesthetic injection or acupuncture for the treatment of back pain. Patients suspected of having coexisting low back pain due to reasons other than musculoskeletal disorders, and patients who had received other treatment for low back pain within 1 month of the start of the trial were excluded.

Twenty-six patients with low back pain (14 male, 12 female) were randomly allocated to an acupuncture group (n = 13) and a local anaesthetic injection group (n = 13) using random selection software (Sample Size 2.0, Blackwell Science Ltd). All the patients were diagnosed using x-ray and MRI. There were 19 patients with lumbar spondylosis deformans, five with spinal canal stenosis, one with spondylosis of the fifth lumbar vertebra and one with intervertebral discopathy, with five presenting lower limb symptoms. All patients were instructed not to receive other treatment during the trial period and not to change the dose or type of drug already being taken 1 month or more before the start of the trial. The trial was conducted in observance of the Helsinki declaration and with the approval of the ethics committee of the Meiji University of Integrative Medicine.

Intervention

Patients in both the acupuncture group and local injection group received treatment at two to five of the most tender points which were determined with palpation at the area where the patient indicated as most painful part in the low back once a week for 4 weeks. For acupuncture, the therapists inserted a stainless steel needle (40 mm

in length and 0.18 mm in diameter, Seirini Co. Shizuoka, Japan) to a depth of 10–20 mm. After verifying the patient experienced a needling sensation, the sparrow pecking method (a kind of basic manipulation technique with repetitive application of lifting and thrusting of the needle) was applied (at a repetition of 1 cycle/s, for a total of 20 s) before removing the needle. For the local anaesthetic injection, the therapists used a 20 gauge needle (25 mm in length and 0.5 mm in diameter, Terumo Corporation, Japan) inserted to a depth of 10–20 mm and removed after injection of the solution, which contained 5 mg of dibucaine hydrochloride/5 ml (Neovitacain, Vitacain Pharmaceutical Co., Ltd). Acupuncture was performed by an acupuncturist with more than 5 years of clinical experience in acupuncture and moxibustion, and the anaesthetic injections were performed by three orthopaedists with more than 10 years of clinical experience.

Evaluation

A 100 mm Visual Analogue Scale (VAS) was used for the subjective evaluation of pain, with 100 mm representing presumed maximum pain and the 0 mm representing no pain. Evaluations were recorded before and after the first treatment, before each subsequent treatment, and at 2 weeks and 4 weeks after completion of treatment by evaluators blinded to the patient's group allocation.

Statistical analysis

All values presented are mean values $\pm$ SD. Baseline characteristics of patients in both groups were compared using the Student *t* test. Within-group changes in VAS pain scores were determined using scores at the time of each evaluation (comparison of baseline values and values at the time of each evaluation). The change in pain score from baseline was determined for each evaluation timepoint (baseline value minus corresponding value at each time period), and the change in pain score at each evaluation was compared between the groups. Within-group and between-group comparisons were tested using the Student *t* test and Bonferroni's adjustment. Changes in the VAS pain scores over the study period in both groups were analysed using repeated measures analysis of variance. The *p* value for the male to female ratio in the two groups was determined using Fisher's exact test. All analyses were computed with Statview V.4.5 (Sas Institute, Japan). Results were considered significant when the *p* value was less than 0.05.

RESULTS

Comparison of the baseline characteristics of patients in the two study groups showed no significant between-group differences in age, gender, duration of disorder and VAS pain scores (table 1). There were no cases of exacerbated low back pain or adverse events after treatment in the two groups, and all participants completed the trial.

Absolute VAS pain scores after intervention and changes in VAS pain score from baseline (baseline value minus corresponding values at each time period) are shown in tables 2 and 3, respectively.

Changes in VAS pain scores after treatment

Both groups showed a significant within-group improvement ($p<0.01$ for acupuncture group, $p<0.05$ for local anaesthetic injection group). A significant interaction was observed between the two groups ($p<0.01$), and the change in VAS pain score was larger in the acupuncture group (figure 1).

Table 1 Baseline patient characteristics

	Acupuncture	Local injection
Number (sex)	13 (male: 6, female: 7)	13 (male: 8, female: 5)
Age (mean $\pm$ SD)	70.8 $\pm$ 9.3	73.6 $\pm$ 5.5
Duration of low back pain (days, mean $\pm$ SD)	399 $\pm$ 735	373 $\pm$ 703
Diagnosis n	Spondylosis deformans 9 Spinal canal stenosis 3 Spondylosis 1	Spondylosis deformans 10 Spinal canal stenosis 2 Discopathy 1
VAS pain score (mm, mean $\pm$ SD)	61.3 $\pm$ 19.0	60.6 $\pm$ 13.8
Other treatment n	Anti-inflammatory poultice 5	Anti-inflammatory poultice 3 Analgesic drug 1

Effect immediately after treatment

VAS pain scores improved significantly in both groups immediately after the first treatment ($p<0.01$ for acupuncture group, $p<0.05$ for local anaesthetic injection group) (table 2). However, the decrease in VAS pain score after treatment differed significantly between the two groups ($p<0.05$) (table 3).

Effect of repeated treatment

The baseline VAS pain scores before the first treatment were compared with scores before the fourth treatment to determine the effect of repeated treatments. A significant improvement was observed in the acupuncture group ($p<0.01$), but there was no significant change in the local anaesthetic injection group ($p=0.21$) (table 2). Furthermore, the decrease in VAS pain score was significantly different between the two groups ($p<0.01$) (table 3).

Sustained effect after completion of treatment

The baseline VAS pain scores before treatment were compared with scores 2 weeks and 4 weeks after completion of treatment to determine the sustained effect.

A comparison of VAS pain scores before treatment and 2 weeks after completion of treatment showed a significant improvement in the acupuncture group ($p<0.01$ for acupuncture group, $p=0.09$ for local anaesthetic injection group) (table 2). Furthermore, there was a significant difference between the two groups in the degree of decrease of VAS pain scores at 2 weeks' follow-up ($p<0.01$) (table 3).

Similarly, a comparison of VAS pain scores before treatment and 4 weeks after completion of treatment showed a significant improvement in the acupuncture group ($p<0.01$ for acupuncture group, $p=0.07$ for local anaesthetic injection group) (table 2). The degree of decrease of VAS pain scores was also significantly different between the two groups ($p<0.05$) (table 3).

Table 2 Visual Analogue Scale pain scores at each time period, measured in mm

	Before treatment	Immediately after first treatment	At the end of treatment course	2 weeks after completion of treatment	4 weeks after completion of treatment
Acupuncture	61.3 $\pm$ 19.0	18.2 $\pm$ 17.2**	16.5 $\pm$ 20.3**	11.9 $\pm$ 21.5**	9.5 $\pm$ 17.1**
Local anaesthetic injection	60.6 $\pm$ 13.8	45.3 $\pm$ 25.1*	44.5 $\pm$ 32.5	41.1 $\pm$ 32.4	38.5 $\pm$ 34.8

Values are mean $\pm$ SD. * $p<0.05$ vs before treatment, ** $p<0.01$.

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Table 3 Change in Visual Analogue Scale pain scores from baseline, measured in mm

	Directly after first treatment	At the end of treatment course	2 weeks after completion of the treatment	4 weeks after completion of the treatment
Acupuncture	43.2 ± 27.0*	44.8 ± 14.5**	49.4 ± 17.0**	51.8 ± 15.8*
Local anaesthetic injection	15.3 ± 20.4	16.2 ± 26.1	19.5 ± 26.8	22.1 ± 28.8

Individual values were calculated as: change equals baseline value minus corresponding value at each time period.

Values are mean ± SD. * $p < 0.05$ vs local anaesthetic injection group, ** $p < 0.01$.

DISCUSSION

Since there were no significant differences in the baseline characteristics (age, gender, duration of disorder and first VAS pain score) of patients in the two study groups, the trial is thought to have been successfully randomised.

Mean age of the patients in the present study was relatively higher than those reported in the other studies involves those with low back pain.²² The difference may be due to difference of demographic patterns between populations, as it is reported that symptom of low back pain is most frequently reported by people whose age is 75 or older.²³

The VAS pain scores significantly improved in both groups immediately after the first treatment. However, there was a significant difference in the degree of decrease between the two groups, with more favourable results seen in the acupuncture group. This showed that both acupuncture and local anaesthetic injection had short-term effects, but acupuncture was more effective.

Both groups showed significant improvement in VAS pain scores over time after repeated treatment. However, there was significant interaction between the groups, indicating a significantly better result in the acupuncture group.

The change in pain score over time with repeated treatments was assessed in terms of cumulative effect (determined by comparing VAS pain scores before treatment and before the fourth treatment) and sustained effect after completion of treatment (determined by comparing VAS pain scores before treatment and 2 weeks and 4 weeks after completion of treatment). Within-group comparisons of both the cumulative and sustained effect indicated a statistically significant improvement in the acupuncture group only. These data suggest that

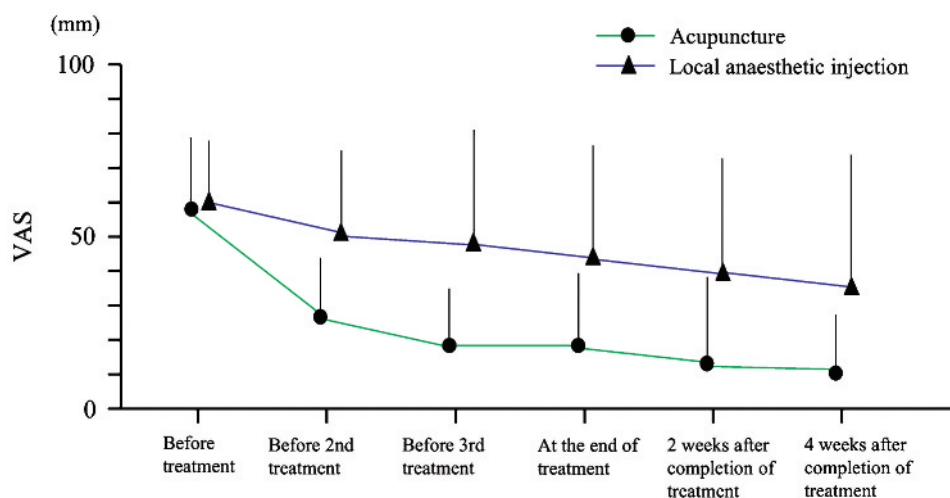
compared with local anaesthetic injection, acupuncture is more effective for the treatment of low back pain in terms of immediate effect, cumulative effect and sustained effect. The difference between the two treatments may be due to a difference in the mechanism of pain suppression.

It is believed that acupuncture simply involves physical stimulation with the insertion of a needle. In contrast, the local anaesthetic injection entails insertion of a needle (physical stimulation) plus the anaesthesia induced by the local anaesthetic. The mechanism of pain suppression of acupuncture is thought to involve descending inhibition by the central nervous system or activation of inhibition in the spinal cord.²⁴ On the other hand, pain suppression in local anaesthesia results from blockade of sensory nerve signals by the anaesthetic.²⁵ The results of this trial show that acupuncture provides significantly more favourable results than local anaesthetic injection in patients with low back pain. For this reason, depending on the type and degree of pain, we believe that stimulation therapy alone may be more effective.

Frost *et al*²⁶ compared the effects of local injection of anaesthetic and saline solution and reported that the saline solution had a more effective analgesic effect. In addition, Byrn *et al*²⁷ compared injections of saline solution and distilled water and reported that distilled water was more effective. Furthermore, in patients with radicular sciatica for which nerve root block was ineffective, Inoue *et al*²⁸ found that electro-acupuncture stimulation in the nerve root region gave more favourable results than anaesthesia. All these reports indicate that stimulation therapy is more effective, supporting the results of our trial. In their discussions, Frost *et al*²⁶ suggested that for the injection of saline solution alone, the physical stimulation produced an analgetic effect. Byrn *et al*²⁷ noted that using hypotonic distilled water to evoke strong C fibre stimulation had an effective action. Although there is a possibility that the local anaesthetic injections used in our trial involves the mechanical stimulation of needle insertion which may cause similar effect of acupuncture needle insertion, treatment with acupuncture was more effective. It is possible that the effect of the mechanical stimulation of the injection needle could be masked by the anaesthetic agent.

However, there is a limitation to interpreting results of the present study due to smaller sample size; several studies regarding effect of acupuncture on low back pain indicated that effect size tends to be smaller as the sample size

Figure 1 Changes in VAS pain scores. Data are expressed as mean (SD). Visual Analogue Scale score for low back pain steadily decreased over the study period in both the acupuncture group ($p < 0.01$) and the local anaesthetic injection group ($p < 0.05$). A significant interaction (Time × Group) with repeated measures analysis of variance was found between the two groups ($p < 0.01$).



Summary box

- This trial compared the effectiveness of acupuncture and local anaesthetic injection at the most painful points in patients with low back pain.
- Acupuncture was superior to local anaesthetic injection for low back pain in terms of immediate, cumulative and sustained effect.
- The difference in the effects of the two treatments may be due to a difference in the mechanism of pain suppression.

increased.^{29 30} Also, we used only one outcome measure to evaluate the effect of acupuncture. These weaknesses should be addressed in future studies.

Taken together, we concluded that acupuncture could be used as an effective, less-invasive, non-pharmacological alternative to local anaesthetic injections, although further trials with larger sample size and multiple outcome measurements might be necessary to obtain more robust evidence in the future.

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