Effects of trigger point acupuncture on chronic low back pain in elderly patients – a sham-controlled randomised trial

Kazunori Itoh, Yasukazu Katsumi, Satoko Hirota, Hiroshi Kitakoji

Abstract

Introduction There is some evidence for the efficacy of acupuncture, but it remains unclear whether trigger point acupuncture is effective. Our objective was to evaluate the effects of trigger point acupuncture on pain and quality of life in chronic low back pain patients compared with sham acupuncture.

Methods Twenty-six consecutive out-patients (17 women, 9 men; age range: 65–91 years) from the Department of Orthopaedic Surgery, Meiji University of Oriental Medicine, with non-radiating low back pain for at least six months and normal neurological examination, were randomised to two groups. Each group received one phase of trigger point acupuncture and one of sham acupuncture with a three week washout period between them, over 12 weeks. Group A (n=13) received trigger point acupuncture in the first phase and sham acupuncture in the second. Group B (n=13) received the same interventions in the reverse order. Outcome measures were pain intensity (visual analogue scale, VAS) and Roland Morris Questionnaire.

Results Nineteen patients were included in the analysis. At the end of the first treatment phase, group A receiving trigger point acupuncture scored significantly lower VAS (P<0.001) and Roland Morris Questionnaire scores (P<0.01) than the sham control group. There were significant within-group reductions in pain in both groups during the trigger point acupuncture phase but not in the sham treatment phase. However, the beneficial effects were not sustained.

Conclusion These results suggest that trigger point acupuncture may have greater short term effects on low back pain in elderly patients than sham acupuncture.

Keywords

Trigger point, chronic low back pain, elderly, randomised controlled trial, acupuncture.

Kazunori Itoh
licensed acupuncturist
Department of Clinical Acupuncture and Moxibustion

Yasukazu Katsumi
professor
Department of Orthopaedic Surgery

Satoko Hirota
licensed acupuncturist
Department of Orthopaedic Surgery

Hiroshi Kitakoji
professor
Department of Clinical Acupuncture and Moxibustion

Meiji University of Oriental Medicine
Kyoto, Japan

Correspondence:
Kazunori Itoh

k_itoh@muom.meiji-u.ac.jp

Introduction

Acupuncture has been frequently applied to chronic low back pain (LBP).[1;2] A number of randomised controlled trials (RCTs) on acupuncture for chronic LBP have already been published.[3-7] Trigger point acupuncture therapy is one of the important treatments for myofascial pain syndrome.[8] Our previous study suggested that deep needling at a trigger point may be more effective on low back pain in elderly patients than standard needling of conventional points.[9] In many studies, direct needling of trigger points appears to be an effective treatment,[8-10] but the hypothesis that needling therapies have efficacy beyond placebo is neither supported nor refuted by the evidence from clinical trials. Therefore, controlled trials are needed to investigate whether needling has an effect beyond placebo on trigger point.

On the other hand, it is possible that problems with the choice of control (sham) might be a major cause of such discrepancies. The importance of the sham-controlled RCT in acupuncture is that it excludes strong placebo effects and clarifies the specific effects of acupuncture. Minimal acupuncture, a shallow and weak needling technique,[11;12] has been proposed as a sham technique, but this procedure is a form of acupuncture practised in Japan. For the purpose of pain relief, the choice of non-acupuncture points as a sham treatment is also a problem because of the existence of diffuse noxious inhibitory control (DNIC) phenomena; it is well established that

painful stimulation inhibits pain, and DNIC has been proposed as a physiological basis of acupuncture analgesia.[13]

We conducted a sham-controlled RCT to evaluate the effectiveness of real acupuncture to trigger points as a treatment for chronic low back pain.

Methods

Patients

Patients aged 65 years or over with a history of low back pain were recruited from the Meiji University of Oriental Medicine Hospital specifically for the study. Inclusion criteria were (1) lumbar or lumbosacral low back pain for a duration of six months or longer; (2) leg pain permitted only if minor severity in comparison to low back pain; and (3) normal neurological examination findings of lumbosacral nerve function, including deep tendon reflexes, plantar response, voluntary muscle action, straight leg raising, and sensory function. Exclusion criteria were (1) major trauma or systemic disease; and (2) other conflicting or on-going treatments. However, patients with medical conditions were included if there had been no change in drugs or dosage for one month or longer.

Patients who gave written informed consent were enrolled and randomly allocated to either group A, who received trigger point acupuncture followed by sham, or group B, who received sham acupuncture followed by trigger point acupuncture, using a computerised randomisation programme. Ethical approval for this study was given by the ethics committee of Meiji University of Oriental Medicine.

Design

The study was a patient- and assessor-blinded, randomised, sham controlled, crossover clinical trial. The two groups received the two interventions in three weekly sessions, with a washout period of three weeks. The overall trial period was 12 weeks, including a final observation period of three weeks.

Patients were blinded to their treatment, being told that they would receive two active treatments in random order. The measurements were performed by an independent investigator who was not informed about the treatment sequence or the treatment the patient received before each measurement.

Table 1 **Treatment point on trigger point acupuncture group**

Muscle	Group A	Group B
quadratus lumborum	5	4
iliopsoas	3	4
piriformis	2	3
gluteus maximus	4	3
iliocostalis lumborum	2	1
gluteus medius	3	4
hamstring	1	2
other	2	2

Interventions

All interventions were given at the site of the trigger point (TrP). This was identified in accessible muscles ideally by the presence of a tender taut band, patient recognition of pain, and local twitch response. In less accessible muscles, the TrP was diagnosed only by tenderness and pain recognition on manual pressure or needling. The involved muscles are listed in Table 1.

For genuine TrP acupuncture, disposable stainless needles (0.2mm×50mm, Seirin, Japan) were inserted into the skin over the trigger point to a depth of 10-40mm, appropriate to the muscle targeted, attempting to elicit a local muscle twitch response using the 'sparrow pecking' technique. After the local twitch response was elicited or a reasonable attempt had been made, the needle was retained for a further 10 minutes. For sham acupuncture, similar stainless needles (0.2mm×50mm) 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.[16] The acupuncturist pretended to insert the needle and to use the sparrow pecking technique, then removed the needle. A simulation of needle extraction was performed after 10 minutes, by touching the patient and noisily dropping a needle into a metal bowl. In group A, the mean number of muscles identified with trigger points was 2.2 (range 1-4) and the number of needles 3.6 (range 2-7). In group B, the mean number of muscles was 2.6 (range 2-5), and needles 3.5 (range 3-8).

The acupuncturist performing all treatments had four years of acupuncture training and seven years of clinical experience.

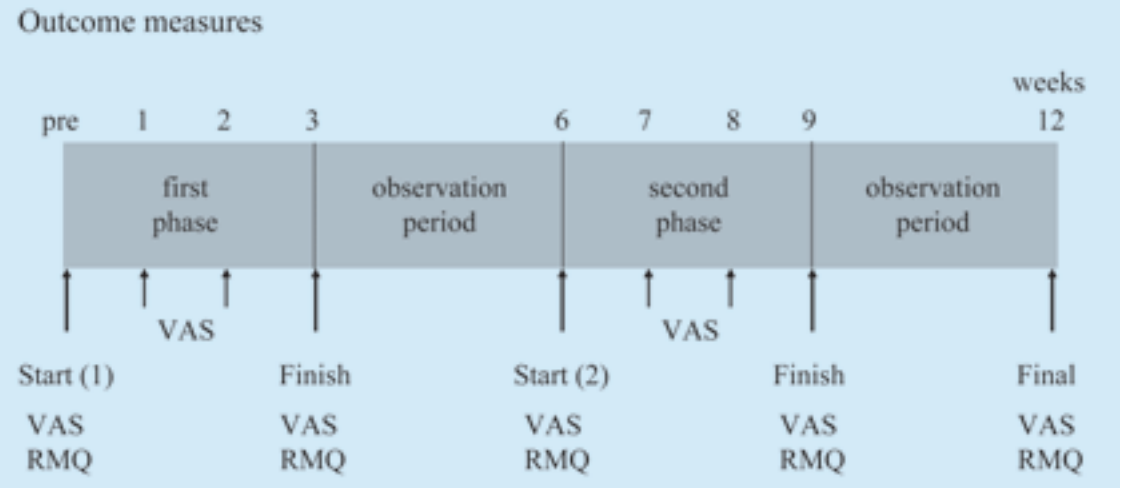

Figure 1 The design of the trial. Evaluation was performed immediately before each treatment. VAS: visual analogue scale, RMQ: Roland Morris Questionnaire.

Evaluation

Primary outcome measures were pain intensity, quantified using a 10cm visual analogue scale (VAS), and pain disability,[17] measured using the Roland Morris Questionnaire (RMQ).[18] The RMQ consists of 24 questions answered yes or no (range 0–24 points, most severe = 24).

The VAS scores were recorded immediately before the first treatment (pre) and one, two, three, six, seven, eight, nine, and 12 weeks after the first treatment. The RMQ measures were assessed before the first treatment and three, six, nine, and 12 weeks after the first treatment. The VAS and RMQ measures were completed by participants immediately before each treatment (Figure 1).

To test blinding, the participants were asked the question 'How did you feel when the acupuncture needle was inserted?' at the end of the first phase. The available responses were: (1) needles were inserted into muscle; (2) needles did not penetrate the skin; and (3) I could not discriminate.

Statistical analysis

The data are reported as means and standard deviation (SD). Repeated measures analysis of variance (ANOVA) was used for the primary measure, a between-group comparison of overall VAS and RMQ scores. To detect within-group differences, repeated measures ANOVA were performed in each group, followed by pairwise comparisons with Sidak correction to maintain the experiment-wise error rate below five percent. Differences between the groups at each time period were analysed using unpaired *t* test with the Bonferroni correction, by which each test performed was judged against a corrected significance level as alpha/c, where c is the number of paired comparisons. The success of blinding was analysed by Fisher's exact test. StatView for Windows (version 5.0) or SYSTAT 11 was used for the statistical analysis. P value of <0.05 was defined as statistically significant.

Results

A total of 26 patients (17 women, 9 men; age range: 65–91 years) were randomised and started treatment (Figure 2). No differences were found between the two groups regarding the variables measured at baseline including age, disease, pain duration, VAS and drug use (Table 2).

Patient progress through the trial is shown in Figure 2. Two patients in group A, and four in group B dropped out as they had no response to treatment, and one patient in group A dropped out due to adverse effects (deterioration of symptoms). The dropout rate was not different among the groups (P=0.66, Fisher's exact test). The analyses were performed on the 19 patients who completed the study.

VAS score

As shown in Figure 3 and Table 3, the mean VAS scores decreased during the TrP acupuncture treatment periods, and there was a statistically significant group-time interaction ($F_{3,51}$=20.2, P<0.001, repeated measures ANOVA).

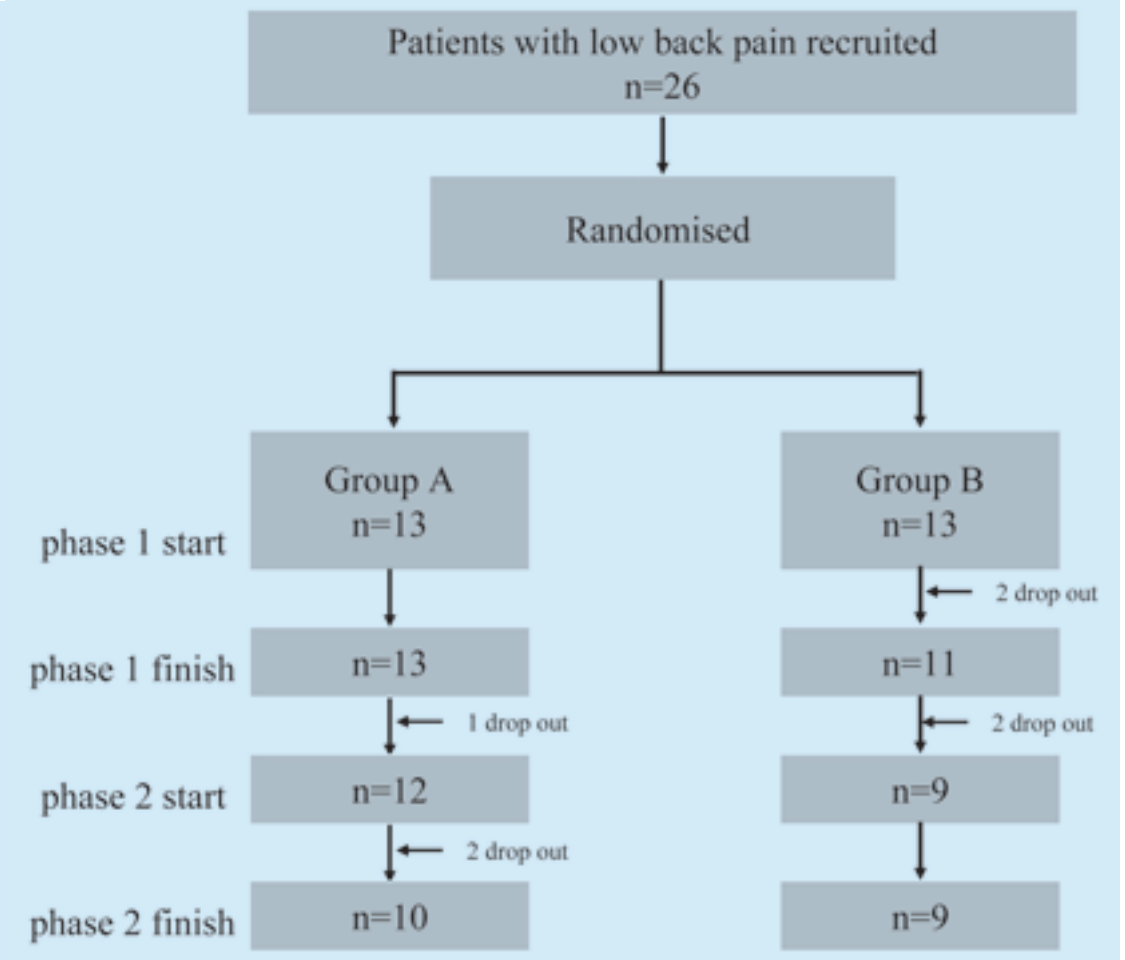

Figure 2 Participant flow in the study. Seven patients who dropped out were excluded from the analysis.

Significant differences between groups A and B were found at weeks two and three (both P<0.001). At week three, the change from baseline also showed statistical significance ($F^{8,72}$=7.17, P<0.01, for overall differences by repeated measures ANOVA, P<0.01 for each comparison with Sidak correction). For group B, although no significant changes in the VAS were found in the first phase, significant differences were found between week six and weeks seven, eight and nine (P=0.049, 0.039, and <0.01, respectively pairwise with Sidak correction).

Table 2 **Patient characteristics**

Group	A		B	
Sample size	10		9	
Age	73.5±10.0		78.8±4.7	
Diagnosis	Spondylosis	9	Spondylosis	8
	Osteoporosis	3	Osteoporosis	3
	Compression Fracture	3	Compression Fracture	3
Pain duration	4.2±3.5 (y)		5.4±6.2 (y)	
VAS (mm)	65.0±13.1		69.0±12.5	
Other treatment	Anti-inflammatory poultice	7	Anti-inflammatory poultice	6
	Analgesic drug	3	Analgesic drug	3
	Vitamin D	1	Vitamin D	3
	Bisphosphonates	2	Bisphosphonates	3

Functional impairment

As shown in Figure 4 and Table 4, mean RMQ scores decreased during the TrP acupuncture periods, with a significant difference in the group-time interaction ($F_{4,68}$=17.0, P<0.01 by repeated measures ANOVA). There was a significant difference between the groups at week three (P<0.01, unpaired *t* test with Bonferroni correction); and the change from baseline in Group A was also significant (P<0.01, pairwise comparison with Sidak correction after repeated measures ANOVA [$F_{4,36}$=9.88, P<0.01]). In group B, there was a significant difference between weeks six and nine

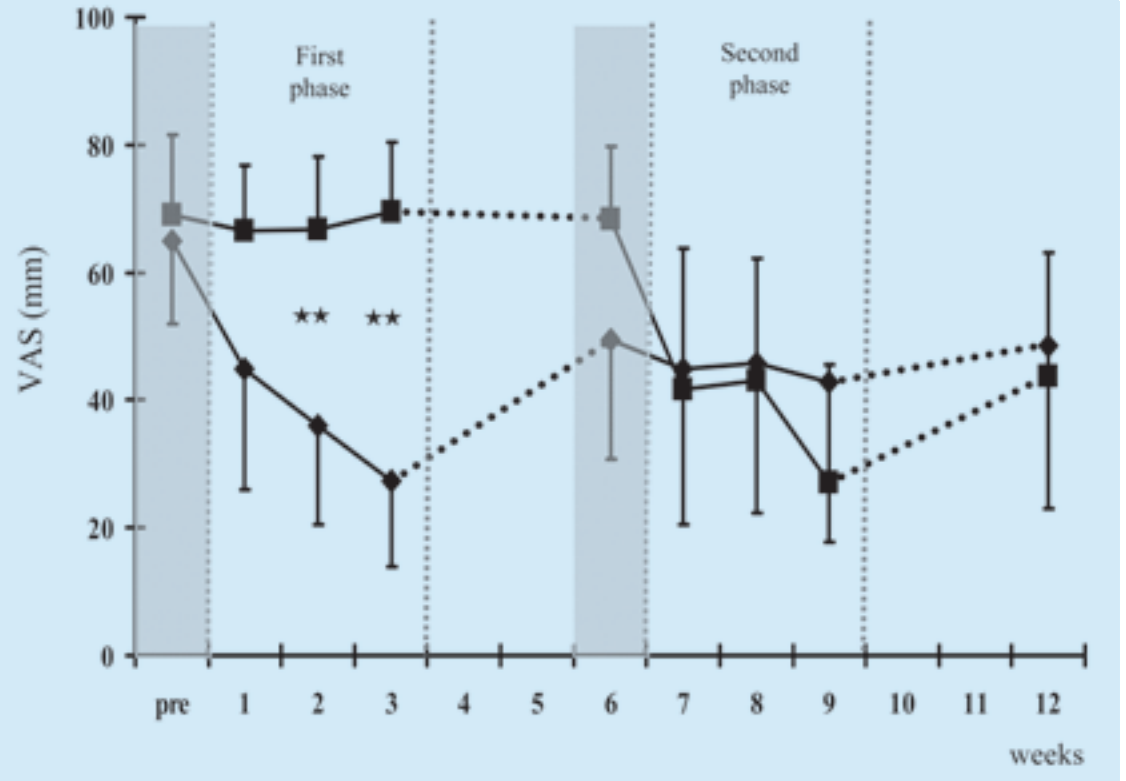

Figure 3 Effect of acupuncture on chronic low back pain by VAS. ■: group A (trigger point–sham treatment, n=10), ▲: group (sham–trigger point treatment, n=9), ★★: P<0.01 (ANOVA inter-group)

Table 3 **Mean pain intensity on VAS**

week	Group A	Group B
pre	65.0±13.1	69.0±12.5
1	44.9±19.0	66.4±10.3
2	36.0±15.6	66.8±11.4
3	27.3±13.5	69.6±10.9
6	49.5±18.8	68.3±11.4
7	44.9±24.5	41.7±22.1
8	45.7±23.4	43.1±19.1
9	42.9±25.0	27.0±18.4
12	48.5±25.6	43.8±19.4

(P<0.01, post hoc pairwise comparison with Sidak correction after repeated measures ANOVA [$F_{4,32}$=29.29, P<0.01]).

In the test of blinding during the first phase, 7/10 (70%) in group A (TrP acupuncture) and 4/9 (44%) in group B (sham acupuncture) believed that they received needle insertion to the muscle; whereas 2/10 (20%) in group A and 3/9 (33.3%) in group B answered that the needle had not penetrated the skin. The difference was not statistically significant (chi-square = 0.78, df=2, P=0.38).

Discussion

In the present study, there was a statistically significant difference between the effects of TrP acupuncture and sham acupuncture on pain and function in low back patients, three weeks after the start of the trial. These results suggest that TrP acupuncture treatment may be more effective than sham acupuncture treatment for low back pain in elderly patients. However, the effects of trigger point acupuncture treatment were not sustained during the three week washout period. The impact of the study is limited by its small size and the numbers of patients who dropped out of treatment.

Effect of trigger point or sham acupuncture on chronic low back pain

The present findings suggest that subjective pain as measured by VAS scores decreases after TrP acupuncture treatment, and these effects tend to accumulate with repeated treatment. On the other hand, the sham procedure was associated with no statistically significant effects.

In a previous systematic review of acupuncture for low back pain, Van Tulder et al included 11 clinical studies, eight of which compared acupoint

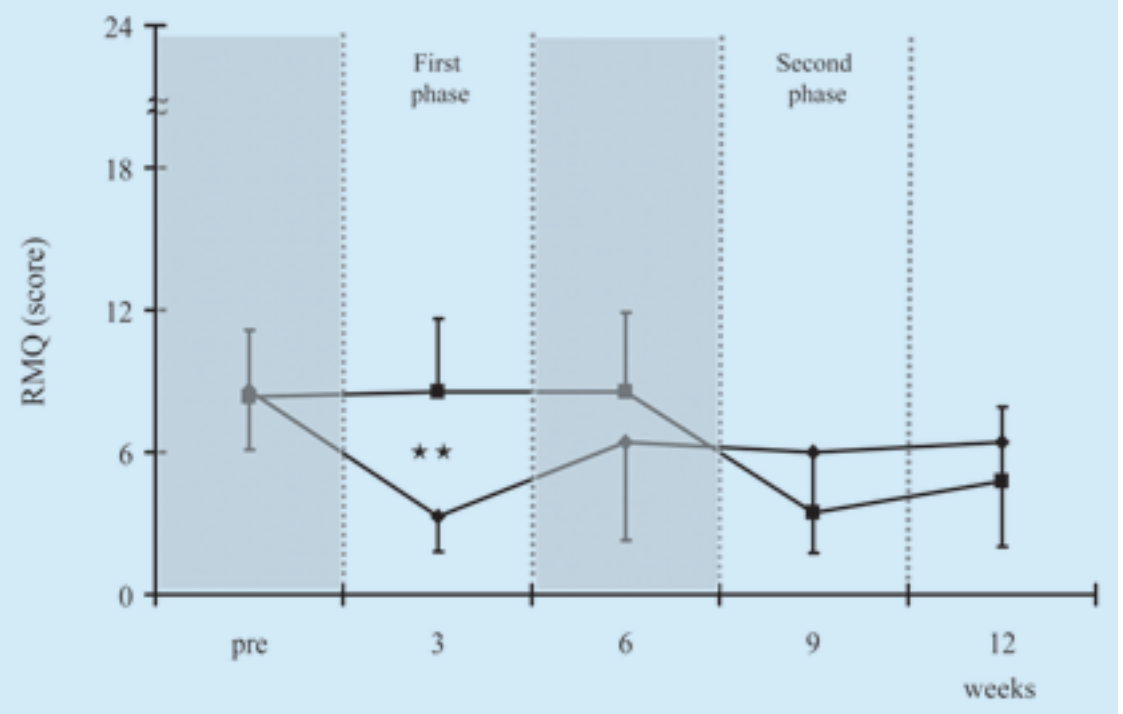

Figure 4 Effect of acupuncture on chronic low back pain by RMQ. ■*: group A (trigger point–sham treatment, n=10),* ▲*: group (sham–trigger point treatment, n=9),* ★★: P<0.01 (ANOVA inter-group)

Table 4 **Mean RMQ on chronic low back pain**

week	Group A	Group B
pre	8.6±2.5	8.3±2.8
3	3.3±1.5	8.6±3.1
6	6.4±4.1	8.6±3.3
9	6.0±4.2	3.4±2.5
12	6.4±4.4	4.8±3.1

Table 5 **Assessment of blinding answers to the question 'How did you feel when the acupuncture needle was inserted ?'**

	Inserted to muscle	Not penetrated skin	Could not discriminate
Group A	7	2	1
Group B	4	3	2

stimulation with sham acupuncture. No significant differences were found between the effects of true and sham stimulation.[2] More recently, reviews by Manheimer and colleagues,[19] and Furlan and colleagues,[20] have found evidence that acupuncture is superior to sham acupuncture, and superior to no treatment, in the short term.

In evaluating the efficacy of acupuncture, the important treatment parameters are the stimulation site, the intensity and the modality of stimulation of the needle. For the assessment of the parameter 'stimulation site', one can vary the number of stimulation sites and their location (traditional acupoint or tender point/trigger point). In most previous studies, the stimulation site has been a traditional acupoint.[4-7] However, in our previous study, we found that treatment at trigger points may be more effective on low back pain in elderly patients than at traditional acupuncture points.[9]

The myofascial trigger point has been defined as a localized, hyperirritable spot in a palpable taut band of skeletal muscle fibres.[14] Important characteristics of a myofascial trigger point include local pain or tenderness, referred pain or referred tenderness, and local twitch response.[15] The acupuncture or dry needling of a myofascial trigger point appears to provide immediate relief of pain. It is obvious that a trigger point is different from a tender point or some acupuncture points. In this study, clinical results indicated that TrP acupuncture treatment has a better analgesic effect than sham acupuncture treatment.

Myofascial trigger points are believed to be sites where nociceptors, such as polymodal receptors, have

been sensitised by various factors. In particular, sensitised nociceptors at the fascia might be possible candidates for localised tenderness.[21;22] Chemical, thermal, and mechanical stimulation of polymodal receptors have also been proposed as a possible mechanism of the analgesic effect of acupuncture and moxibustion.[23] Therefore, acupuncture stimulation of myofascial trigger points may produce greater activation of sensitised polymodal receptors, resulting in stronger effects on pain relief.

Sham acupuncture technique and experimental design

The importance of sham-controlled studies to control for the strong placebo effects of acupuncture has been debated.[11;24] The various control interventions used in acupuncture studies include no-treatment controls,[25] mere pricking (without penetration),[26] minimum acupuncture (shallow and weak needling),[27] mock TENS (without current pulse),[28] and so on.

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 procedure as with the real acupuncture. Blinding in this study appears to have been successful.

Recently, Streitberger and Kleinhenz developed a unique sham acupuncture needle.[29] 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,[30] it is worth examining its usefulness for future RCTs of acupuncture.

We utilised a two-by-two crossover design to assess the effect of the trigger point acupuncture against a sham procedure, and could detect an effect of trigger point acupuncture. This design has the advantage of permitting a 'within-subject' analysis for which a small sample size may be adequate.[31] Since the between-subjects effect was significantly different in the first phase but not in the second phase, one explanation is that there was a certain carry over effect of the trigger point acupuncture and a small sustained effect of the treatment, which could be further explored in future studies.

Acknowledgments

The authors wish to thank Dr K Kawakita for his constructive comments on the manuscript, and to H Ochi and N Ishizaki for their help during this study. This study was supported by a grant from the Ministry of Health and Welfare (H14- Choju-029).

Reference list

1. Ernst E, White AR. Acupuncture for back pain: a meta-analysis of randomized controlled trials. *Arch Intern Med* 1998;158(20):2235-41.
2. van Tulder MW, Cherkin DC, Berman B, Lao L, Koes BW. The effectiveness of acupuncture in the management of acute and chronic low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 1999;24(11):1113-23.
3. Molsberger AF, Mau J, Pawelec DB, Winkler J. Does acupuncture improve the orthopedic management of chronic low back pain – a randomized, blinded, controlled trial with three months follow up. *Pain* 2002;99(3):579-87.
4. Leibing E, Leonhardt U, Koster G, Goerlitz A, Rosenfeldt JA, Hilgers R, et al. Acupuncture treatment of chronic low-back pain – a randomized, blinded, placebo-controlled trial with nine-month follow-up. *Pain* 2002;96(1-2):189-96.
5. Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulker S. A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly. *Pain* 1999;82(1):9-13.
6. Carlsson CP, Sjölund BH. Acupuncture for chronic low back pain: a randomized placebo-controlled study with long-term follow up. *Clin J Pain* 2001;17(4):296-305.
7. Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L. Comparison of superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study. *Clin J Pain* 2002;18(3):149-53.
8. Cummings TM, White AR. Needling therapies in the management of myofascial trigger point pain: a systematic review. *Arch Phys Med Rehabil* 2001;82(7):986-92.
9. Itoh K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients - a blinded RCT. *Acupunct Med* 2004;22(4):170-7.
10. Birch S, Jamison RN. Controlled trial of Japanese acupuncture for chronic myofascial neck pain: assessment of specific and nonspecific effects of treatment. *Clin J Pain* 1998;14(3):248-55.
11. Vincent C, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med* 1995;88(4):199-202.
12. Richardson PH, Vincent CA. Acupuncture for the treatment of pain: a review of evaluative research. *Pain* 1986;24(1):15-40.
13. Bing Z, Villanueva L, Le Bars D. Acupuncture and diffuse noxious inhibitory controls: naloxone-reversible depression of activities of trigeminal convergent neurons. *Neuroscience* 1990;37(3):809-18.
14. Simons DG, Travell JG, Simons PT. *Travell & Simons' Myofascial Pain & Dysfunction. The Trigger Point Manual. Volume 1. Upper Half of Body.* 2nd ed. Baltimore: Williams & Wilkins; 1999.
15. Hong C-Z. Myofascial trigger points: pathophysiology and correlation with acupuncture points. *Acupunct Med* 2000;18(1);41-7.

16. Nabeta, T, Kawakita K. Relief of chronic neck and shoulder pain by manual acupuncture to tender points – a sham-controlled randomized trial. *Complement Ther Med* 2002;10(4):217-22.
17. Scott J, Huskisson EC. Graphic representation of pain. *Pain* 1976;2(2):175-84.
18. Roland M, Morris R. A study of the natural history of back pain. Part 1: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8(2):141-4.
19. Manheimer E, White A, Berman B, Forys K, Ernst E. Meta-analysis: acupuncture for low back pain. *Ann Intern Med* 2005;142(8):651-63.
20. Furlan AD, van Tulder MW, Cherkin DC, Tsukayama H, Lao L, Koes BW et al. Acupuncture and dry-needling for low back pain. *Cochrane Database Syst Rev* 2005;(1):CD001351.
21. Itoh K, Kawakita K. Effect of indomethacin on the development of eccentric exercise-induced localized sensitive region in the fascia of the rabbit. *Jpn J Physiol* 2002;52(2);173-80.
22. Kawakita K. Polymodal receptor hypothesis on the peripheral mechanisms of acupuncture and moxibustion. *Am J Acupunct* 1993;21(4):331-338.
23. Itoh K, Okada K, Kawakita K. A proposed experimental model of myofascial trigger points in human muscle after slow eccentric exercise. *Acupunct Med* 2004; 22(1);2-12.
24. Vincent CA, Richardson PH. The evaluation of therapeutic acupuncture: concepts and methods. *Pain* 1986:24(1):1-13.
25. Coan RM, Wong G, Coan PL. The acupuncture treatment of neck pain: a randomized controlled study. *Am J Chin Med* 1981;9(4):326-32.
26. Johansson A, Wenneberg B, Wagersten C, Haraldson T. Acupuncture in treatment of facial muscular pain. *Acta Odontol Scand* 1991;49(3):153-8.
27. Vincent CA. A controlled trial of the treatment of migraine by acupuncture. *Clin J Pain* 1989;5(4):305-12.
28. Petrie JP, Hazleman BL. A controlled study of acupuncture in neck pain. *Br J Reumatol* 1986;25(3):271-5.
29. Streitberger K, Kleinhenz J. Introducing a placebo needle into acupuncture research. *Lancet* 1998;352(9125):364-5.
30. Kaptchuk T. Placebo needle for acupuncture. *Lancet* 1998;352(9132):992.
31. Everitt B.S. *The Cambridge Dictionary of Statistics*. Cambridge: Cambridge University Press; 1998. p. 87.