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,[7,8] but this procedure is a form of acupuncture practiced in Japan, and our previous study suggested that shallow and weak needling has analgesic effects.[9] 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.[10,11]

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.
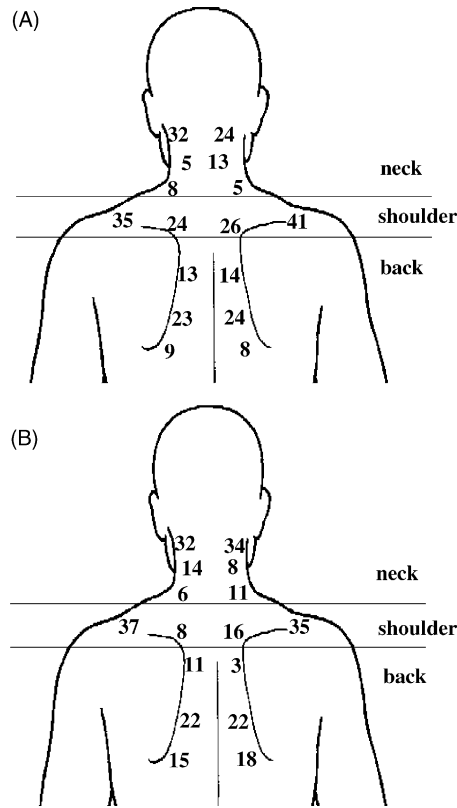
(A)

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

	Just before the first treatment	9 days after third treatment
Whole		
AG	52.8 ± 25.5	44.1 ± 20.5
SG	51.9 ± 22.5	49.7 ± 23.5
Neck		
AG	60.5 ± 15.0	43.3 ± 19.7
SG	48.8 ± 27.9	46.8 ± 25.4
Shoulder		
AG	54.2 ± 21.8	44.4 ± 21.3
SG	50.1 ± 22.9	52.9 ± 24.5
Back		
AG	46.8 ± 20.9	36.6 ± 18.3
SG	46.6 ± 19.5	37.6 ± 20.9

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 sim-

ilar 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).

VAS score

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
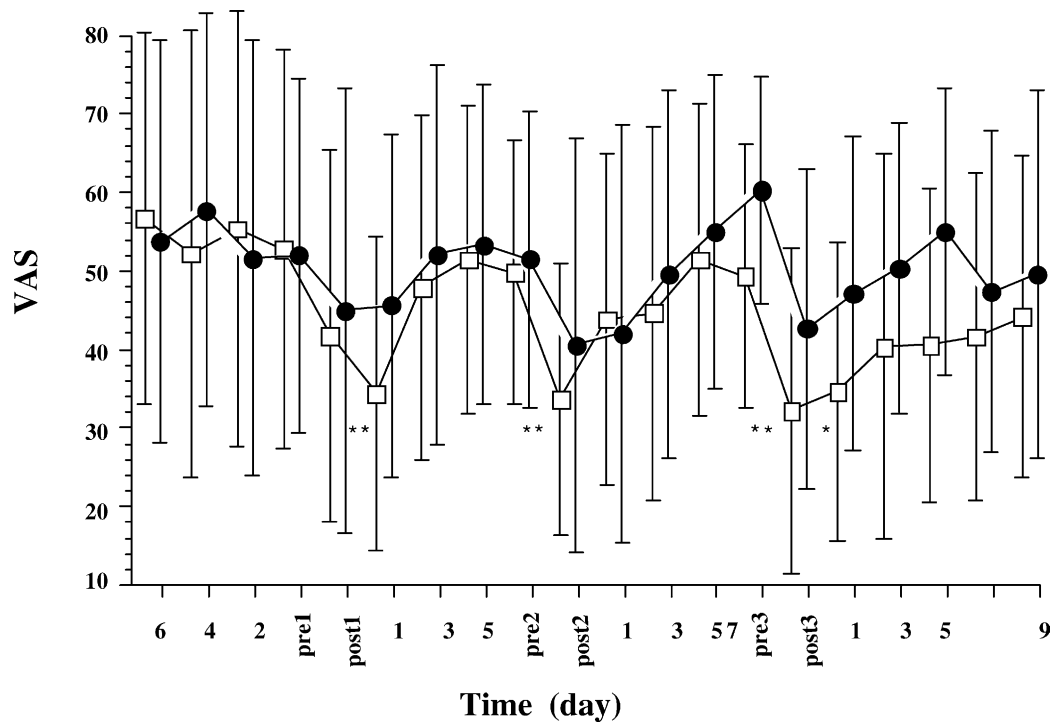

Fig. 2 Overall VAS scores for pain before and after the repeated acupuncture (empty squares) or sham (solid circles) treatments. Data are mean ± S.D. *$P < 0.05$ and **$P < 0.01$, Dunnett's multiple test: compared with baseline scores. No statistically significant difference was detected between the AG and SG groups.

Table 2 Pressure pain threshold (PPT) measured before and immediately after three treatments with acupuncture (AG) or sham (SG)

	n	1		n	2		n	3	
		Before	**After**		**Before**	**After**		**Before**	**After**
Neck									
AG	27	1.7 ± 0.7	2.1 ± 0.9[**]	22	1.6 ± 0.8	1.9 ± 1.1[**]	25	1.9 ± 1.5	2.6 ± 1.9[*]
SG	26	1.6 ± 0.9	1.6 ± 1.0	27	1.8 ± 1.1	1.9 ± 1.1	24	1.1 ± 0.4	1.3 ± 0.5[*]
Shoulder									
AG	45	2.4 ± 1.8	2.9 ± 2.3[**]	45	2.4 ± 1.8	3.0 ± 2.5[**]	45	2.6 ± 2.0	3.1 ± 2.0[**]
SG	44	2.0 ± 1.4	2.1 ± 1.3	47	2.0 ± 1.5	2.2 ± 1.8[**]	37	1.2 ± 0.6	1.4 ± 0.5[**]
Back									
AG	24	2.3 ± 0.8	2.7 ± 1.1[**]	40	2.6 ± 1.4	3.3 ± 1.5[**]	31	2.8 ± 1.3	3.4 ± 1.3[**]
SG	27	1.9 ± 1.0	2.1 ± 1.0[**]	27	2.0 ± 0.8	2.1 ± 0.8	30	1.6 ± 0.6	1.8 ± 0.5

Data are shown as mean ± S.D.
[*] $P < 0.05$.
[**] $P < 0.001$, paired t-test, before vs. after.

from just before each treatment in both groups although the time courses were different. In AG, statistically significant differences compared with baseline were observed immediately after the second and third treatments and 1 day after the first and third treatments (Dunnett's multiple test) and tended to last longer with the successive treatments. In SG group, no statistical significant differences were found.

PPT

The PPTs measured before and after each treatment (a total of six measurements) tended to increase after the treatment in AG. Table 2 shows that the PPTs of the neck, shoulder, and back were significantly increased after every treatment in AG (before versus after, $P < 0.01$, paired t-test). In SG, on the contrary, statistically significant changes in both directions were observed.

Assessment of the blinding technique

In the present procedure, 65% in AG and 53% in SG answered that they received the needle insertion to the muscle, whereas 24% in AG and 35% in SG answered they had no penetration of the needle (Table 3). There was no significant difference between the two groups (chi-square = 0.6, $P = 0.74$).

Table 3 Assessment of blinding answers to the question "How did you feel when the acupuncture needle was inserted?" in acupuncture (~AG) and sham (SG) groups

	Inserted to muscle	Not penetrated skin	Could not discriminate
AG	11	4	2
SG	9	6	2

No significant difference between AG and SG was found (chi-square = 0.6, $P = 0.74$).

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.[12] 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.[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).[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. For example, Baldry illustrated the clinical effect of treating them with many case reports.[15] However, 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.[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.[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.[7,18] There are many RCTs of acupuncture in which various control groups have been employed, such as no-treatment controls,[3,19,20] mere pricking (without penetration),[5,21,22] minimum acupuncture (shallow and week needling),[7,23] mock TENS (without current pulse),[2,6,24–26] 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 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[27] and Kleinhenz et al.[28] developed a unique sham acupuncture. 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,[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.[4] Thus, the effects of acupuncture treatment in both groups were probably augmented by volunteer bias, to some extent.

REFERENCES

1. David J, Modi S, Aluko AA, Robertshaw C, Farebrother J. Chronic neck pain: a comparison of acupuncture treatment and physiotherapy. Br J Rheumatol 1998; 37: 1118–1122.
2. Petrie JP, Langley GB. Acupuncture in the treatment of cervical pain. A pilot study. Clin Exp Rheumatol 1983; 1: 333–335.
3. Coan RM, Wong G, Coan PL. The acupuncture treatment of neck pain: a randomized controlled study. Am J Chin Med 1982; 9: 326–332.
4. 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: 248–255.
5. Moore ME, Berk SN. Acupuncture for chronic shoulder pain: an experimental study with attention to the role of placebo and hypnotic susceptibility. Ann Intern Med 1976; 84: 381–384.
6. Petrie JP, Hazleman BL. A controlled study of acupuncture in back pain. Br J Rheumatol 1986; 25: 271–275.
7. Vincent C, Lewith G. Placebo controls for acupuncture studies. J R Soc Med 1995; 88: 199–202.
8. Richardson PH, Vincent CA. Acupuncture for the treatment of pain: a review of evaluative research. Pain 1986; 24: 15–40.
9. Nabeta T, Furuta T, Kitakouji H, Kawakita K. Randomized controlled pilot study of acupuncture on neck stiffness. J Jpn Soc Acupunct 1997; 47: 173–181 [in Japanese].
10. Murase K, Kawakita K. Diffuse noxious inhibitory controls in anti-nociception produced by acupuncture and moxibustion on trigeminal caudalis neurons in rats. Jpn J Physiol 2000; 50: 133–140.

11. 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: 809–818.

12. Kawakita K. Palpable hardenings—a survey of questionnaire on the experienced acupuncturists—[no abstract is available]. J Jpn Soc Acupunct 1986; 36: 36–41 [in Japanese].

13. Melzack R, Stillwell DM, Fox EJ. Trigger points and acupuncture points for pain: correlations and implications. Pain 1977; 3: 3–23.

14. Wolf F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the multicenter criteria committee. Arthritis Rheum 1990; 33: 160–172.

15. Baldry PE, Thompson JW. Acupuncture, trigger points and musculoskeletal pain. Churchill Livingstone, 1993.

16. Kawakita K, Miura T, Iwase Y. Deep pain measurement of the pulse algometry in human subjects. Pain 1991; 44: 235–239.

17. Kawakita K. Polymodal receptor hypothesis on the peripheral mechanisms of acupuncture and moxibustion. Am J Acupunct 1993; 21: 331–338.

18. Vincent CA, Richardson PH. The evaluation of therapeutic acupuncture: concepts and methods. Pain 1986; 24: 1–13.

19. Coan RM, Wong G, Su IK, Yick CC, Wang L, Ozer FT, Coan PL. The acupuncture treatment of low-back pain: a randomized controlled study. Am J Chin Med 1980; 8: 181–189.

20. Johansson A, Wenneberg B, Wagersten C, Haraldson T. Acupuncture in treatment of facial muscular pain. Acta Odontol Scand 1991; 49: 153–158.

21. Junnila SYT. Acup, Acupuncture therapy for chronic pain. A randomized comparison between acupuncture and pseudo-acupuncture with minimal peripheral stimulus. Am J Acupunct 1982; 10: 259–262.

22. Jensen BL, Melsen B, Jensen SB. The effects of acupuncture on headache measured by reduction in number of attacks and use of drugs. Scand J Dent Res 1979; 87: 373–380.

23. Vincent CA. A controlled trial of the treatment of migraine by acupuncture. Clin J Pain 1989; 5: 305–312.

24. Lewith GT, Field J, Machin D. Acupuncture compared with placebo in post-herpetic pain. Pain 1983; 17: 361–368.

25. Dowson DI, Lewith G, Machin D. The effects of acupuncture versus placebo in the treatment for headache. Pain 1985; 21: 35–42.

26. Deluze C, Bosia L, Zirbs A, Chantraine A, Vischer TL. Electroacupuncture in fibromyalgia: results of a controlled trial. BMJ 1992; 305: 1249–1252.

27. Streitberger K, Kleinhenz J. Introducing a sham needle into acupuncture research. Lancet 1998; 352: 364–365.

28. Kleinhenz J, Streitberger K, Windeler J, GuBbacher A, Mavridis G, Martin E. Randomised clinical trial comparing the effects of acupuncture and a newly designed sham needle in rotator cuff tendinitis. Pain 1999; 83: 235–241.

29. Kaptchuk T. Sham needle for acupuncture. Lancet 1998; 352: 992.