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RESEARCH ARTICLE

Randomized Trial of Trigger Point Acupuncture Treatment for Chronic Shoulder Pain: A Preliminary Study

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Abstract

There is evidence for the efficacy of acupuncture treatment for chronic shoulder pain, but it remains unclear which acupuncture modes are most effective. We compared the effect of trigger point acupuncture (TrP), with that of sham (SH) acupuncture treatments, on pain and shoulder function in patients with chronic shoulder pain. The participants were 18 patients (15 women, 3 men; aged 42–65 years) with nonradiating shoulder pain for at least 6 months and normal neurological findings. The participants were randomized into two groups, each receiving five treatment sessions. The TrP group received treatment at trigger points for the muscle, while the other group received SH acupuncture treatment on the same muscle. Outcome measures were pain intensity (visual analogue scale, VAS) and shoulder function (Constant–Murley Score: CMS). After treatment, pain intensity between pretreatment and 5 weeks after TrP decreased significantly ($p < 0.001$). Shoulder function also increased significantly between pretreatment and 5 weeks after TrP ($p < 0.001$). A comparison using the area under the outcome curves demonstrated a significant difference between groups ($p = 0.024$). Compared with SH acupuncture therapy, TrP therapy appears more effective for chronic shoulder pain.

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1. Introduction

Shoulder pain is an important medical and socioeconomic problem in the western world, with between 7% and 26% of the population reporting shoulder problems at any one time [1]. The presence of pain and stiffness in the shoulder can lead to an inability to work and/or to carry out domestic and recreational activities, thus creating a high burden of disease for both the individual and society [2].

Pain and stiffness of the shoulder is commonly caused by rotator cuff disorders including tendonitis and bursitis, by adhesive capsulitis, and by osteoarthritis of the glenohumeral joint [3]. The normal course of the disease consists of a gradual or sudden onset, accompanied by night pain and pain on moving the affected joint. The mobility of the shoulder joint then becomes progressively more limited, until in many cases a “frozen” or stiff shoulder is the result. The process, according to most of the literature, is generally “self-limiting”, lasting for about 1–3 years. Nevertheless, a significant number of patients suffer from a residual, clinically detectable restriction of movement beyond 3 years [4]. The common treatments for shoulder pain are NSAIDs, physiotherapy, injections, and conservative “wait and see” [5]. Unfortunately, none of these treatments is clearly proven to be effective for chronic shoulder pain in the long run, calling for new treatment strategies to improve the situation of chronic shoulder pain sufferers [4,5].

Worldwide, chronic shoulder pain is considered one of the indications most amenable to treatment with acupuncture [6–10]. A small number of clinical and methodologically diverse trials have been published recently that show little evidence to support or refute the use of acupuncture for chronic shoulder pain [11]. However, whether the effect varies depending on the difference in the acupuncture technique has not clearly been demonstrated.

It is generally accepted that the acupuncture treatment administered in the studies conducted so far, have been based on clinical practice rather than empirical evidence. The method of point selection in published trials seems to be more simple and formulaic than that used in the standard acupuncture practice at our clinic. We believe that the response to acupuncture and therefore, the success of a trial, depend substantially on the choice of and the number of points treated.

The main aim of this study was to determine if acupuncture at trigger points is an effective treatment for chronic shoulder pain, when compared with sham (SH) treatment at trigger points.

2. Methods

The design of this study was a blinded, SH-controlled, randomized clinical trial, in which one group received acupuncture treatment and the other SH acupuncture treatment. Patients aged ≥ 40 years, with a history of shoulder pain, were recruited from the Meiji University of Integrative Medicine Hospital specifically for the study. The patients were outpatients in whom chronic shoulder pain had been clinically diagnosed. Inclusion criteria were: (1)

shoulder pain lasting for ≥ 6 months; (2) no neurological disorders causing shoulder pain; (3) an average pain score of 50 mm or on a 100-mm visual analogue scale (VAS) in the pre month; (4) age between 40 years and 70 years; (5) no referred pain from the cervical spine; (6) no osteoarthritis of the glenohumeral joint or systemic bone and joint disorder (e.g., rheumatoid arthritis); (7) no history of shoulder surgery; (8) no other current therapy involving analgesics; (9) had not received acupuncture in the last 6 months; and (10) insufficient response to the medications prescribed by their orthopedic specialist.

The patient could continue to use their medications as they had before enrolment. Exclusion criteria were major trauma or systemic disease, and other conflicting or ongoing treatments.

Patients who gave written informed consent were enrolled and randomly allocated using a computerized randomization program, to the trigger point acupuncture (TrP), or SH treatment groups. Each patient received a total of five treatments, one per week, each lasting 30 minutes, and was followed-up for 20 weeks from the first treatment.

Patients were blinded to their treatment. They were told before randomization that they would be allocated to one of two groups. 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. Patients were asked to cover their eyes with an eye mask to blindfold them, and to ensure that they avoided being aware of the SH procedure.

Ethical approval for this study was given by the ethics committee of the Meiji University of Integrative Medicine.

2.1. Trigger point acupuncture group

The trigger point acupuncture (TrP) group received acupuncture treatment at trigger points. The correct application of the technique requires experience in palpation and localization of taut muscle bands and myofascial trigger points. Precise needling of active myofascial trigger points provokes a brief contraction of muscle fibers. This local twitch response should be elicited for successful therapy, but it may be painful and posttreatment soreness is frequent [12,13]. In this study, the most important muscles of the neck and superior limb were examined for myofascial trigger points (Table 1).

Disposable stainless steel needles (0.2 mm \times 50 mm, Seirin, Sizuoka, Japan) were inserted into the skin over the trigger point to a depth of 5–15 mm, appropriate to the muscle targeted, attempting to elicit a local muscle twitch response using the so called “sparrow pecking” technique. After the local twitch response was elicited, or a reasonable attempt made, the needle was retained for a further 10 minutes. The mean number of insertions was 4.1.

2.2. Sham acupuncture group

The sham (SH) group received SH treatment at trigger points. The methods of choosing trigger points were the same. For the SH group, similar stainless steel needles (0.2 mm \times 50 mm) were used, but the tips had been cut off

Table 1 Muscles treated in the two trigger point acupuncture groups.

Muscle	Trigger point group	Sham group
<i>Musculus trapezius</i>	3	4
<i>M. supraspinatus</i>	4	6
<i>M. infraspinatus</i>	6	6
<i>M. teres minor</i>	4	3
<i>M. teres major</i>	2	2
<i>M. subscapularis</i>	5	6
<i>M. latissimus dorsi</i>	1	2
<i>M. pectoralis major</i>	2	2
<i>M. pectoralis minor</i>	2	1
<i>M. biceps brachii</i>	2	3
Other	2	3

to prevent the needle from penetrating the skin. The cut ends were smoothed with sandpaper manually under clean conditions [14]. The acupuncturist pretended to insert and manipulate the needle: place the needle with a guide tube over the designated point and tap the top of the needle handle and then remove the tube while holding the needle tip with the thumb and the forefinger of the left hand and thrust and withdraw the needle with the right hand, which holds the needle handle (sparrow pecking technique). A simulation of needle extraction was performed after 10 minutes, by touching the patient and noisily dropping needles into a metal case.

To facilitate blinding, we used an eye mask. The mean number of insertions was 4.4. The treatments were performed by two acupuncturists who had 4 years of acupuncture training and 3 or 10 years of clinical experience.

2.3. Evaluation

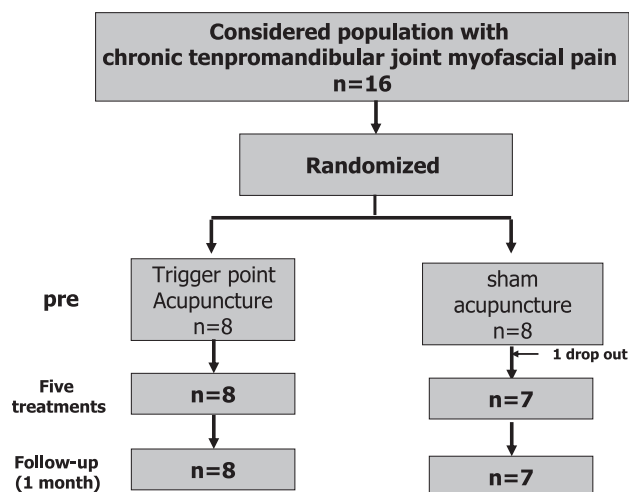
Primary outcome measures were pain intensity, quantified using a 100 mm VAS, and pain disability [15], measured using the Constant–Murley Score (CMS) [15,16]. The total CMS consists of nine questions (range 0–100 points, the worst condition being 100).

The VAS measures were assessed immediately before the first treatment and 1, 2, 3, 4, 5, 10, and 20 weeks after the first treatment. The CMS measures were assessed before the first treatment and 5, 10, and 20 weeks after the first treatment. The VAS and SMS measures were completed by participants immediately before each treatment (Fig. 1).

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

2.4. Statistical analysis

The data are reported as mean \pm standard deviation (mean \pm SD). Dunnett’s multiple comparison test was

**Figure 1** Participation flow in the study. One patient was excluded after she dropped out.

applied to detect significant changes within each group. To compare the results of two groups, the area under the curve (AUC) of the pain VAS was calculated from the summation of the time–response curves for individual patients. The AUC data (arbitrary units) for each group were used for group comparison by a one-way analysis of variance (ANOVA) followed by *post hoc* multiple comparisons using the Bonferroni correction.

Assessment of the success of blinding was analyzed using a χ^2 test. SPSS software for Windows (version 11.0, SPSS Japan Inc., Shibuya, Tokyo, Japan) or Systat 11 (Systat Software, Washington, Chicago, USA) was used for the statistical analysis. A *p* value <0.050 was considered as statistically significant.

3. Results

3.1. Patient characteristics

Eighteen patients (15 women, 3 men; aged 42–65 years) were randomized to two groups and administered treatment (Fig. 2). No differences were found between the two groups in the variables measured at baseline, including age, disease, pain duration, VAS, and drug use (Table 2).

Patient progress through the trial is shown in Fig. 2. One patient in the SH group dropped out, as they had no response to treatment. The drop-out rate was not different among the groups (*p* = 0.31, Mann–Whitney *U* test). The analyses were performed on the 17 patients who completed the study.

3.2. VAS score

Pain intensity decreased at weeks 4–5 in the TrP group, when compared with pretreatment levels. These improvements persisted for 10 weeks after cessation of the treatment in the TrP group. The mean VAS score decreased significantly in the TrP group (*p* < 0.001 in the TrP by repeated measures ANOVA; Fig. 2).

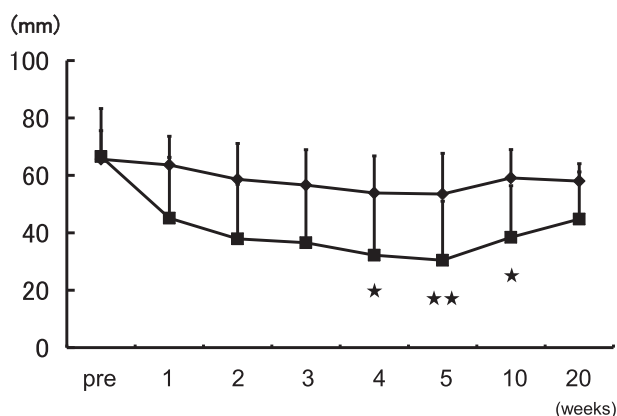


Figure 2 This shows the effect of acupuncture on visual analogue scale (VAS) score for chronic shoulder pain. The pain intensity was lower at weeks 4–5 in the trigger point acupuncture (TrP) group when compared to pretreatment scores. ■: TrP group ($n = 8$), ◆: sham acupuncture group ($n = 7$), ** $p < 0.01$, * $p < 0.05$.

The AUCs for pain intensity (VAS score) are shown in Fig. 3. The score was significantly lower in the TrP group than in the SH group ($p = 0.024$).

3.3. Functional impairment

The reduction in the CMS score was higher at week 5 in the TrP group, when compared with that at pretreatment. These improvements persisted for 1 month after cessation of the treatment. The mean CMS score showed a significant reduction in the TrP group ($p < 0.001$ in the TrP; Fig. 4).

The AUCs for functional impairment (CMS score) are shown in Fig. 5. The score was not significantly higher in the TrP group than in the SH group ($p = 0.311$).

3.4. Assessment of the blinding technique

In the present procedure, 77.8% in the TrP group and 75.0% in the SH group stated that they received the needle insertion to the muscle, whereas 22.2% in the TrP group and 25.0% in the SH group stated they received no penetration of the needle. There was no significant difference between the two treatment types ($\chi^2 = 0.18$, $p = 0.89$).

Table 2 Characteristics and baseline values of patients in the two groups.

	Trigger point group	Sham group
Sample size	8	8
Age (y)	55.0 ± 12.6	59.3 ± 15.6
Pain duration (y)	2.1 ± 1.6	2.2 ± 1.6
Visual analogue scale (mm)	67.3 ± 18.2	66.9 ± 10.1
Constant–Murley Score	57.0 ± 9.9	57.6 ± 8.0
Drug user	0	0

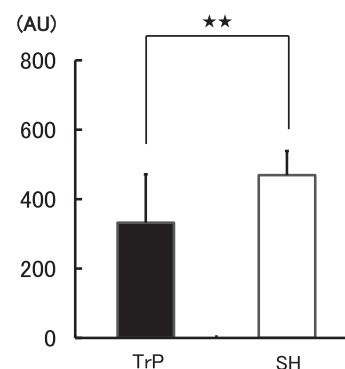


Figure 3 The columns indicate the area under the curve (AUC, arbitrary units) for changes in the pain visual analogue scale (VAS) score in the two groups. During the observation period, improvement was greater in the TrP group than the SH group ($p = 0.024$). ** $p < 0.01$.

4. Discussion

In the present study, there was a statistically significant difference between the TrP and SH acupuncture treatments, 5 weeks after the first treatment. These results suggest that TrP treatment is more effective than SH acupuncture treatment for chronic shoulder pain.

In many cases, chronic shoulder pain is correlated with deformation of the shoulder joint and muscle tension around the joint [17]. A wide range of treatments are used, including drugs, physical medicine methods, and manual treatments [4,5]. Acupuncture treatment has been used for pain relief for a long time. Several studies have examined the efficacy of acupuncture treatment for shoulder pain; however, the results have been mixed [11,17].

In evaluating the efficacy of acupuncture, three important parameters are the site, mode, and intensity of the stimulation. For assessing the ‘stimulation site’ parameter, one can define the number of stimulation sites and their location (traditional acupoint or tender/trigger point). In

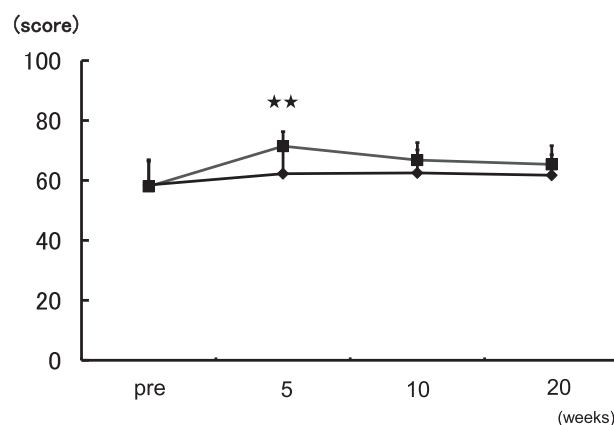


Figure 4 The effect of acupuncture on Constant–Murley Score (CMS) score indicating shoulder function. The CMS score was lower at weeks 5–10 in the trigger point acupuncture (TrP) group when compared to pretreatment scores. ■: TrP group ($n = 9$), ◆: sham acupuncture group ($n = 8$), $p > 0.05$.

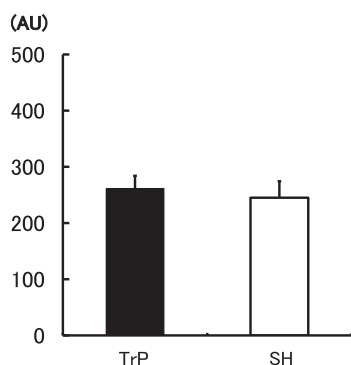


Figure 5 The columns indicate the area under the curve (AUC, arbitrary units) for changes in shoulder function in the two groups. The trigger point acupuncture (TrP) group, the score was higher than the sham (SH) group score, but the difference was not statistically significant ($p = 0.311$).

most previous studies, the stimulation sites were traditional acupuncture points [18–20]. However, our results suggest that the response to trigger points is greater than the response to treating traditional acupoints or non-trigger points [21,22]. These results suggest that the site of stimulation is important, and the acupuncture stimulation of myofascial trigger points might be most effective for chronic shoulder pain patients.

The importance of the sham-controlled, randomized clinical trials, to control for the strong placebo effects of acupuncture, has been debated [14,23,24]. Nabeta and Kawakita [14] found that there are many acupuncture randomized clinical trials in which various control groups have been employed, such as no-treatment controls [25], mere pricking (without penetration) [26], minimum acupuncture (shallow and weak needling) [27], and mock transcutaneous electrical nerve stimulation (without current pulse) [28,29]. However, in most previous studies, positive results were obtained in studies that used a non-acupuncture control group [25,30], and negative results tended to be reported in those that used SH acupuncture or mock transcutaneous electrical nerve stimulation [31,32]. Therefore, the choice of control might be very important. The SH 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 for the genuine acupuncture. Blinding in this study appears to have been successful. Although a few patients withdrew from the study, we considered the influence on the results to be minimal, because the number of withdrawals in each group did not differ much (1/7 in SH and 0/8 in TrP).

4.1. Effectiveness of the trigger point as a treatment site for acupuncture

The myofascial trigger points have often been used in the treatment of myofascial pain syndrome. The myofascial trigger point has been defined as a highly localized and hyperirritable spot in a palpable taut band of skeletal muscle fibers [13]. Important characteristics of myofascial trigger points include local pain or tenderness, referred

pain or referred tenderness, and local twitch response [12,13]. Acupuncture or dry needling of a myofascial trigger point appears to provide immediate relief of pain related to that myofascial trigger point [21,33,34]. However, the effects of TrP on chronic shoulder pain remain unclear.

In this study, clinical results suggested that the analgesic effect of TrP is better than that of SH acupuncture. Myofascial active trigger points are supposed to be sites where nociceptors, such as polymodal-type receptors, have been sensitized by various factors [35,36]. In particular, sensitized nociceptors might be a cause of localized tenderness, referred pain, and local twitch response [37,38]. Moreover, the trigger point insertion of the needle (but not always acupuncture point insertion) affects sensitized nociceptors [38–40]. Thus, acupuncture stimulation of myofascial active trigger points may produce greater activation of sensitized polymodal-type receptors, resulting in greater pain relief.

TrP, compared with standard acupuncture, provides significantly more relief of chronic low back pain and neck pain [21,22], but not of chronic knee pain [41]. These findings suggest that the myofascial pain near joints in contrast to other types of chronic pain, may depend on different factors, such as inflammation and joint pain. Therefore, the effects of standard acupuncture on chronic shoulder pain may be as effective as TrP. However, the limited sample size and poor quality of these studies highlights and supports the need for large scale, good quality placebo controlled trials in this area [42].

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