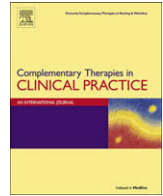




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A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain

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A B S T R A C T

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Objective: The present study tests whether a combined treatment of acupuncture and transcutaneous electrical nerve stimulation (TENS) is more effective than acupuncture or TENS alone for treating chronic low back pain (LBP).

Methods: Thirty-two patients with chronic LBP were randomly allocated to four groups. The acupuncture group (ACP) received only acupuncture treatment at selected acupoints for low back pain; the TENS group (TENS) received only TENS treatment at pain areas; the acupuncture and TENS group (A&T) received both acupuncture and TENS treatments; the control group (CT) received topical poultice (only when necessary). Each group received specific weekly treatment five times during the study. Outcome measures were pain intensity in terms of visual analogue scale (VAS) and QOL of low back in terms of Roland-Morris Disability Questionnaire (RDQ).

Results: The ACP, TENS and A&T groups all reported lower VAS and RDQ scores. Significant reduction in pain intensity ($P < 0.008$) and significant improvement in QOL ($P < 0.008$) were shown in the A&T group.

Conclusion: Combined acupuncture and TENS treatment is effective in pain relief and QOL of low back improvement for the sampled patients suffering from chronic LBP.

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1. Introduction

Low back pain (LBP) is a major health problem in modern society.¹ Seventy to eight-five percent of the population will experience LBP at some time in their lives.¹ Each year, 5–10% of the workforce is off work because of their LBP, but most of them are off for less than seven days. Almost 90% of all patients with acute LBP recover quite rapidly, regardless of therapy. The remaining 10% are at risk of developing chronic pain and disability and account for more than 90% of the social costs for back incapacity.² The proportion of elderly patients who have LBP is greater than that of young adults.

On the other hand, anti-inflammatory drugs used to treat the symptoms of this disorder usually have various side effects.³ When drugs are not adequately effective, replacement treatment is often recommended.⁴ Patients with chronic pain increasingly seek alternative methods for pain relief, particularly transcutaneous electrical nerve stimulation (TENS)^{5,6} and acupuncture.^{7,8} TENS has the advantage of being efficacious, inexpensive, simple and essentially free of side effects. TENS may also be used at home by

patients themselves due to its portability and simplicity. Several studies examined the efficacy of acupuncture and TENS treatment for such conditions; however, the results were inconclusive.^{4–8} Acupuncture and TENS were found effective in treating pain and dysfunction in patients with LBP.^{4–8} A systematic review covering seven randomised controlled trials concluded that acupuncture and TENS were effective in reducing pain; however, differences in efficacy between acupuncture and TENS were inconclusive.^{4–8}

The present study aims to test whether TENS or a combined treatment of acupuncture and TENS is more effective than acupuncture or TENS alone for treating chronic non-specific LBP in older patients.

2. Methods

2.1. Patients

Outpatients aged 60 years or older with LBP were recruited from the Meiji University of Oriental Medicine Hospital. Inclusion criteria for the present study were: (1) lumbar or lumbosacral low back pain for six months or longer; (2) no radiation of low back pain; (3) normal neurological findings of lumbosacral nerve, including deep tendon reflexes, plantar response, voluntary muscle action, straight leg raising, and sensory function; and (4) not receiving acupuncture

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treatment for more than six months. Exclusion criteria were: (1) major trauma or systemic disease; and (2) receiving conflicting or ongoing co-interventions. Patients under drug treatment were included if there had been no change in medicine and its dosage for one month or longer. This study was approved by the Ethics Committee of the Meiji University of Integrative Medicine.

All enrolled patients gave their written informed consent. According to a block randomised allocation table (generated by Sample Size, version 2.0, Int), the enrolled patients were allocated to (1) the control (CT) group, (2) the acupuncture (ACP) group, (3) the transcutaneous electrical nerve stimulation (TENS) group or (4) the acupuncture and TENS (A&T) group.

2.2. Design

The design of this study was a randomly controlled clinical trial using a block randomised procedure. Each patient received a total of five treatments, once per week, and follow-up was measured for ten weeks after the first treatment.

2.3. Treatment

2.3.1. Control (CT) group

The CT group patients did not receive any specific treatment, but when necessary, were allowed to use topical poultice containing methylsalicylic acid.

2.3.2. Acupuncture (ACP) group

The ACP group patients received acupuncture treatment at selected acupoints for 15 min on the affected LBP. The selected acupoints are widely accepted for treating LBP,^{9–12} namely Shenshu (BL23), Dachangshu (BL25), Ciliao (BL32), Weizhong (BL40), Kunlun (BL60), huantiao (GB30) and Yanglingquan (GB 34). Disposable stainless steel needles (0.2 mm × 40 mm, Seirin Co Ltd) were inserted into the muscle to a depth of 10 mm using ‘sparrow pecking’ acupuncture technique (alternate pushing and pulling of the needle) by acupuncturists who had four years of acupuncture training and three to eight years of clinical experience. When the subject felt dull pain or the acupuncture sensation (*de qi*) was achieved, the needle manipulation was stopped and the needle was left in place for ten more minutes.

2.3.3. Transcutaneous electrical nerve stimulation (TENS) group

The TENS group patients received treatment at the affected LBP for 15 min from a single-channel portable TENS unit (model HV-F3000, OMRON Healthcare Co Ltd, Japan), which sends between two electrodes a premixed amplitude-modulated frequency of 122 Hz (beat frequency) generated by two medium frequency sinusoidal waves of 4.0 and 4.122 kHz (feed frequency). Surface disposable electrodes of 809 mm² and 5688 mm² were placed on the point with the most tenderness and the near side of the point. Two electrodes were different in size (ratio: 1:7). The smaller one was placed on the site of tenderness. The intensity of TENS was adjusted so that a tingling sensation 2–3 times of the subject’s sensory threshold was produced.

2.3.4. Acupuncture and transcutaneous electrical nerve stimulation (A&T) group

The treatment for the A&T group combined the treatments for the ACP and TENS groups. The patients received 15 min of TENS, and then 15 min of acupuncture treatment at the affected LBP.

We confirmed that the subjects in all groups were not taking any other co-interventions including analgesics, anti-inflammatory agents or poultice containing methylsalicylic acid during the study period.

2.4. Evaluation

Primary outcome measures were: (1) pain intensity, quantified with a 10 cm visual analogue scale (VAS, 0–100 mm) and (2) pain disability measured with the Roland Morris Questionnaire (RDQ, 0–24 points).¹³ The RDQ consists of 24 questions each with two possible responses.

The VAS scores were measured immediately before the first treatment and subsequently at one, two, three, four, five and ten weeks after the first treatment. The RDQ scores were measured immediately before the first treatment and subsequently five and ten weeks after the first treatment. Each VAS and RDQ score was measured immediately before treatment of the specified week.

2.5. Statistical analysis

Repeated measures analysis of variance (ANOVA) was used to study the changes in the VAS and RDQ scores in the three groups. Changes in the time course among groups were considered significant when the interaction was significant at a level of 0.008 (0.05/6). After detection of significant changes in the overall time course with repeated measures ANOVA, pair comparisons were detected with Bonferroni correction. StatView for Windows (version 5.0) or SYSTAT 10 (SYSTAT Inc) was used for the statistical analysis. The results with *P* values of less than 0.05 were considered statistically significant.

3. Results

3.1. Patients

A total of 32 patients (20 women, 12 men; aged 61–81 years) were randomly allocated to four groups for specific treatment. No significant difference was found in baseline variables including age, disease, pain duration, and VAS among the four groups.

One patient in the ACP, two patients in the TENS group, one patient in the A&T group, and one patient in the CT group dropped out as they had not responded to the respective treatment. In addition, one patient in the A&T group dropped out due to adverse effects (*i.e.* deterioration of symptoms). The dropout rate was not significantly different among the groups. The analyses were performed on the 26 patients who completed the study and provided required information (see Fig. 1).

3.2. Pain intensity scores (VAS)

The mean VAS scores decreased in all groups during treatment, although the exact time courses varied (see Table 1). In the A&T group, the pre-treatment (0-week) VAS score and 4-week or 5-week VAS score were significantly different ($P < 0.008$ by Bonferroni multiple comparisons). However, differences between the pre-treatment (0-week) scores and 5-week scores of the ACP, TENS and CT groups were not statistically significant.

During the first five weeks of treatment, while the ACP and A&T groups all reported lower mean pain intensity than the CT group, the only statistically significant reduction was in A&T group.

3.3. RDQ scores

The RDQ scores decreased in all groups during treatment, although the exact time courses varied (see Table 2). In the A&T group, the pre-treatment (0-week) RDQ score and 5-week RDQ score were significantly different ($P < 0.008$ by Bonferroni multiple comparisons). By the end of the fifth week of treatment, the ACP, TENS and A&T groups reported lower RDQ scores than the CT group.

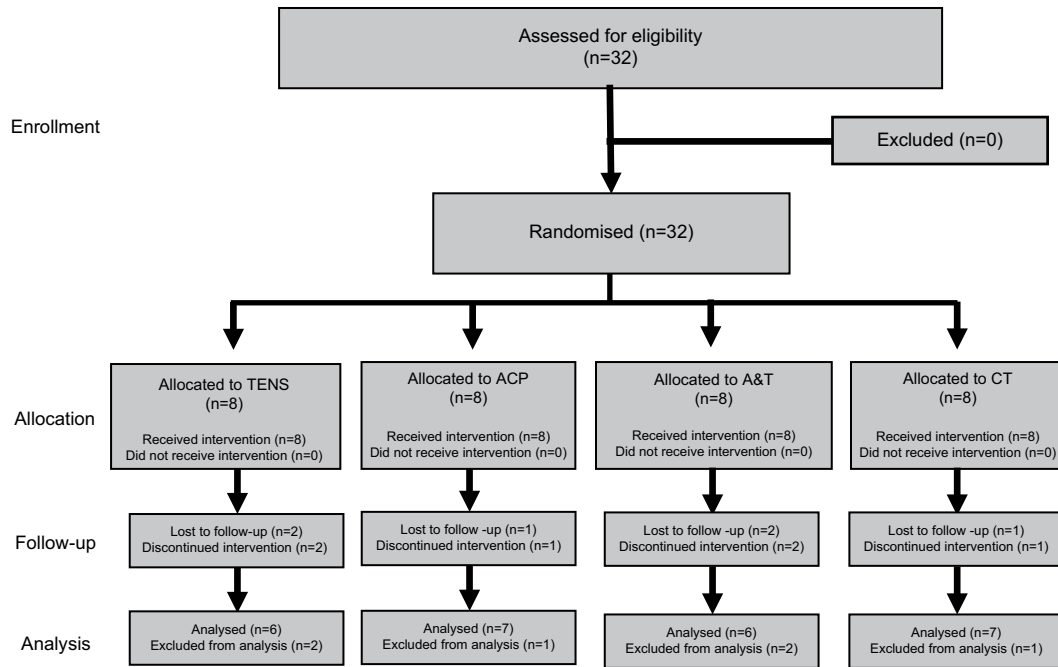


Fig 1. Participation flow in the study.

Table 1
Pain intensity scores (VAS).

Week	TENS (n = 6)	ACP (n = 7)	A&T (n = 6)	CT (n = 7)
0	63.8 (16.5)	60.0 (19.8)	62.3 (12.2)	63.7 (19.0)
1	61.0 (24.1)	47.6 (18.5)	53.2 (8.6)	58.3 (21.6)
2	57.7 (27.2)	47.4 (24.0)	48.0 (6.1)	57.4 (19.7)
3	55.5 (23.5)	43.9 (21.7)	44.8 (5.6)	55.4 (19.7)
4	51.5 (25.7)	39.1 (27.6)	40.8 (5.7)*	56.3 (21.0)
5	53.2 (25.1)	37.4 (25.9)	36.6 (8.0)*	53.1 (27.9)
10	58.0 (23.7)	43.3 (25.7)	49.2 (10.3)	58.1 (28.9)

Data are expressed as mean (SD).

* $P < 0.008$.

Table 2
Roland Morris Questionnaire (RMQ) scores.

Week	TENS (n = 6)	ACP (n = 8)	A&T (n = 6)	CT (n = 7)
0	8.2 (4.1)	7.9 (3.1)	6.8 (1.2)	9.0 (4.9)
5	6.2 (3.4)	5.4 (3.4)	3.8 (0.8)*	7.3 (4.3)
10	7.5 (3.6)	6.7 (4.8)	6.5 (1.6)	7.7 (4.6)

Data are expressed as mean (SD).

* $P < 0.008$.

However, the differences between the treatment groups were not statistically significant.

4. Discussion

TENS and acupuncture are non-pharmacological treatment methods for a variety of pain conditions. This pilot study assessed the effects of acupuncture and TENS on chronic LBP for later clinical trials.

The ACP, TENS and A&T groups showed decreases in pain intensity (VAS scores) compared to the CT group during treatment (see Table 1). The treatment groups showed lower RDQ scores than that of the CT group at week 5 of treatment (see Table 2). These results suggest that acupuncture and TENS treatments have positive effects on the QOL of the chronic LBP patients, and that A&T

treatment was significantly more effective in terms of VAS and RDQ scores than other treatments.

The present study demonstrated that acupuncture and TENS treatments were effective in pain relief. TENS is a common modality for treating musculoskeletal pain.¹⁴ TENS excited large-diameter afferent fibres.¹⁵ According to the gate control theory,¹⁶ TENS may stimulate the large-diameter afferent fibres, which may reduce the transmission of pain signals through the small nociceptive afferent fibres, thereby inhibiting pain discrimination and perception. TENS has been shown to produce antinociceptive effects similar to those of acupuncture^{17,18} with slow onset and gradual offset that persists after the stimulation stops.¹⁹ Acupuncture excited small-diameter afferent fibres.^{20,21} Similar to descending inhibition and/or diffuse noxious inhibitory controls (DNICs) in the brain system, acupuncture may stimulate the small-diameter afferent fibres, which may reduce the transmission of pain signals, thereby inhibiting pain discrimination and perception.²² Moreover, acupuncture is used as an effective treatment for improving lumbar function such as range of motion.¹⁰ It is possible that acupuncture affects tension and blood flow in the muscle. The present study demonstrated that acupuncture was effective in improving the QOL of LBP patients.

Our other studies consistently showed that combined treatment of acupuncture and TENS was more effective than individual treatments on Knee osteoarthritis.²³ TENS was effective for the immediate relief of pain, while acupuncture was effective in long-term pain relief and improvement of patients' QOL. In the present study, the A&T group reported lower mean pain intensity and lower mean RDQ scores than other groups. Therefore, treatment of chronic pain may need combined treatment of acupuncture and TENS.

5. Conclusion

The present study clearly demonstrated that combined acupuncture and TENS treatment is effective for pain relief in terms of VAS and QOL improvement in terms of RDQ in patients suffering from chronic LBP. Large scale clinical trials are warranted.

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