

Randomised Controlled Trial Comparing the Effectiveness of Electroacupuncture and TENS for Low Back Pain: A Preliminary Study for a Pragmatic Trial

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Summary

The objective of this study was to compare the effectiveness of electroacupuncture and TENS for low back pain when the electroacupuncture is applied in a clinically realistic manner. The study was designed as an evaluator-blinded randomised controlled trial (RCT). The study was performed at the Tsukuba College of Technology Clinic in Japan. Twenty subjects, who suffered from low back pain (LBP) without sciatica, were recruited, using leaflets in Tsukuba city. Subjects were allocated to either an electroacupuncture (EA) group (10 patients) or a transcutaneous electrical nerve stimulation (TENS) group (10 patients). The procedure for EA was in accordance with standard practice at our clinic. The main outcome measures were a pain relief scale (100mm visual analogue scale: VAS) and a LBP score recommended by the Japanese Orthopaedic Association (JOA Score). Mean VAS value during the 2-weeks experimental period of the EA group was significantly smaller than that of the TENS group (65mm vs 86mm; 95% CI, 4.126 – 37.953). JOA Score in the EA group improved significantly while that in the TENS group showed no change. Although some placebo effect may be included, EA appeared more useful than TENS in the short-term effect on low back pain. We suggest that more realistic acupuncture interventions based on standard practice should be employed in pragmatic RCTs.

Key words

Acupuncture, electroacupuncture, transcutaneous electrical nerve stimulation, randomised controlled trial, low back pain

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Introduction

Acupuncture has been frequently applied to low back pain (LBP).¹ A number of randomised controlled trials (RCTs) on acupuncture for LBP have already been published.^{2,3} According to systematic reviews of the relevant RCTs,^{2,3} conclusions regarding the efficacy of acupuncture are contradictory. This maybe because the quality of the trials is generally low. It has been suggested that further investigations with rigorously designed RCTs are needed to demonstrate a convincing conclusion. In recent years the comparability of acupuncture RCTs seems to have gradually improved. However, the quality of acupuncture interventions in RCTs is controversial in terms of external validity, in other words, whether it is actually used in the same way in day-to-day practice.⁴

Recently a multi-centre RCT, comparing electroacupuncture (EA) and transcutaneous

electrical nerve stimulation (TENS), was published in Japan.^{5,6} This trial was designed and conducted rigorously in partnership with specialists in clinical trials. The results showed that there was no difference between EA and TENS for LBP. However, the method of point selection in this trial seemed to be more simple and formulary than that used in the standard acupuncture practice at our clinic. We hypothesised that sensitivity of an acupuncture trial substantially depends on the choice and the number of points needed. Employing acupuncture method based on standard practice as an intervention may improve the sensitivity of the acupuncture RCTs. In order to assess this hypothesis, we conducted a pragmatic RCT of acupuncture for LBP.

Methods

This study was approved by the Ethics Committee of Tsukuba College of Technology (TCT) Clinic.

All interventions and evaluations were conducted at the TCT clinic.

Subjects

Twenty patients were recruited, from November 1998 to February 1999, by distributing leaflets in the central area of Tsukuba city. Applicants met with our orthopaedic physician in order to assess their eligibility. All the applicants underwent X-ray examination of the lumbar spine. Inclusion criteria were: (1) low back pain without sciatica, (2) at least a 2-week history of LBP, and (3) over twenty years old. Exclusion criteria were: (1) radiculopathy or neuropathy in the lower extremity, (2) fracture, tumour, infection or internal disease, (3) other general health problems, and (4) other conflicting or ongoing treatments. Informed consent was taken from patients according to the ICH/GCP.⁷

Allocation

Patients were randomly allocated by a research coordinator into the EA or TENS group. An independent controller prepared an allocation table and sealed envelopes. Computer-generated random numbers were used to make a sequence of sealed envelopes containing the code of intervention, and the assigned envelope was opened at the patient's entry into the trial.

Interventions

The procedure for EA was in accordance with that employed in standard practice at the TCT clinic. TENS was chosen as a control intervention as a conservative physical therapy currently practiced in Japan.

Patients in both groups were treated twice a week for two weeks, i.e. four sessions in total. Selection of the treatment points was based on our usual manner in daily practice: tenderness and palpable muscle bands detected on the lower back and the buttock. Four points bilaterally (i.e. eight points in total) were used for each treatment. Points most frequently used were BL23 and BL26.

In the EA group, two types of disposable stainless steel needles (Seirin Kasei Co. Ltd., Japan) were used: 0.20mm in diameter and 50mm in length, and 0.24mm in diameter and 60mm in length. Practitioners chose appropriate needles for the patient's stature and volume of subcutaneous

fat. Needles were inserted into the muscles. The average insertion depth was approximately 20mm. Electro-stimulation was applied to the inserted needles with an electronic stimulator (LFP7000, Zen Iryoki Corp., Japan.), which is used in daily practice at the TCT clinic. Stimulation, with a frequency of 1Hz, was applied for 15 minutes. The intensity was adjusted to the maximum comfortable level, and muscle contraction was observed. Press tack needles (Seirin Jr[®]; Seirin Kasei Co. Ltd., Japan) were inserted after EA at four of the eight chosen points in each session and left in situ. Press tack needles are typically put on acupoints superficially for several days and then removed. The Seirin Jr[®] press tack needle has a 1.3mm-long needle tip projecting from the sticky side of a small round adhesive dressing.

In the TENS group, gel type disposable electrodes of size 20x30mm were used for eight points. Electro-stimulation was applied in the same manner as that in the EA group. The intensity was adjusted to the maximum comfortable level, and muscle contraction was observed. After each session, a poultice containing methyl salicylic acid, menthol and antihistamine was prescribed to be applied at home in between treatments to the low back region.

Outcome assessment

Three outcome measures were recorded: (1) Pain relief scale (PRS);⁸ (2) Back pain profile recommended by Japanese Orthopaedic Association (JOA score);⁹ and (3) occurrence of adverse events. The primary end point was reduction of PRS and the secondary end points were changes in JOA score and occurrence of adverse events.

Regarding the PRS, a 100mm visual analogue score (VAS) was used. One end of the VAS was labelled 'back pain severity at the start of the study', and the other end was labelled 'no pain at all'. The patients were asked to rate their average pain level of the previous day everyday.

JOA score is the most general and frequently used quantitative scale for LBP in Japan. It consists of six categories. Since we focused on LBP without sciatica or neuropathy, we used two of these categories: subjective symptoms and restriction of daily activities (Table 1). The full score for this method is 20 points. An independent

Table 1 Low back pain score recommended by the Japanese Orthopaedic Association (JOA Score)¹⁰
(Two categories out of six were selected: totally 20 points)

I. Subjective Symptoms (9 points: item B was not used in the present trial)	
A. Low Back Pain	
a. None	3
b. Occasional mild pain	2
c. Frequent mild or occasional severe pain	1
d. Frequent or continuous severe pain	0
C. Gait	
a. Normal	3
b. Able to walk farther than 500 metres	2
c. Unable to walk farther than 500 metres	1
d. Unable to walk farther than 100 metres	0

III. Restriction of ADL (14 points)

ADL	Severe restriction	Moderate restriction	No restriction
a. Turn over while lying	0	1	2
b. Standing	0	1	2
c. Washing	0	1	2
d. Leaning forwards	0	1	2
e. Sitting (about 1 hour)	0	1	2
f. Lifting or holding heavy objects	0	1	2
g. Walking	0	1	2

evaluator, who was an orthopaedic doctor, blinded to the allocation, scored each subjects prior to the first treatment and three days after the last treatment.

Acupuncture therapists recorded adverse events, based on observation and interview, at each treatment session. The evaluator also recorded events at the final clinical assessment. Data from withdrawn patients were also included in the analysis of adverse events.

Statistics

Regarding PRS and JOA scores, repeated measures analysis of variance was used for between-group analysis. The level of significance was $P < 0.05$. Chi-square test and t-test were used for baseline analysis. Calculations were performed using the statistical software package StatView for windows ver. 5 (SAS Institute Inc., Cary, USA).

Results

Patients profiles

Twenty patients were enrolled. They were randomised into two groups: EA group (10 patients) and TENS group (10 patients). During the course of the trial one female patient was withdrawn from the EA group due to influenza. Thus nine patients in the EA group and 10 patients in the TENS group completed the trial (Figure 1).

There was no significant age difference between the two groups: the average age was 47 years (ranging from 34 to 61) in the EA group and

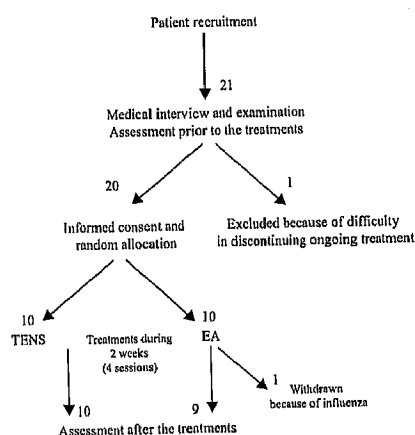


Figure 1. Participant flow

43 years (ranging from 26 to 65) in the TENS group. There were no significant differences in height, weight, baseline JOA score, history of LBP, female/male ratio or experience of acupuncture between the two groups (Table 2).

Pain relief scale

Figure 2 shows changes in the PRS. There was a statistically significant difference between groups ($p = 0.02$) and change in VAS over time ($p < 0.01$), while there was no significant group by time interaction ($p = 0.10$). The average VAS during the intervention period was 65mm in the EA group and 86mm in the TENS group (the difference between the two groups was 21mm: 95% CI, 4.126 – 37.953mm).

Table 2 Baseline characteristics of patients

	EA (n=9)	TENS (n=10)	p-value
Age (years)*	47 ± 10	43 ± 13	0.47
Female/male ratio	8 / 1	8 / 2	0.99
No (%) of acupuncture experienced patients	1 (11%)	3 (30%)	0.64
Height (cm)*	158.6 ± 7.2	159.0 ± 6.6	0.89
Weight (kg)*	57.4 ± 8.6	56.4 ± 6.6	0.77
JOA score *	16.3 ± 2.3	15.6 ± 3.7	0.62
Duration of pain (in days) *	2900 ± 1983	3120 ± 3306	0.86

* mean ± standard deviation

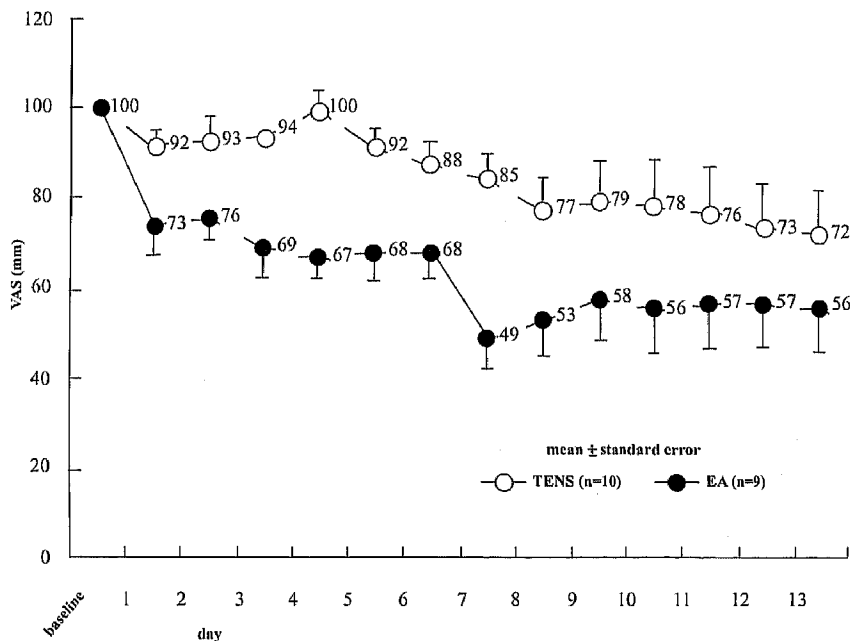


Figure 2 Changes of Pain Relief Scale (VAS)

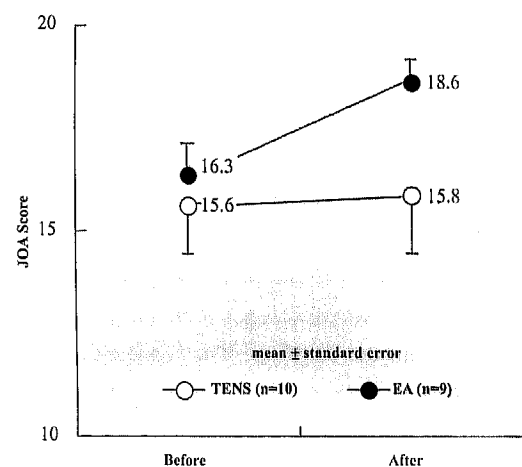


Figure 3 Changes of JOA Score

JOA Score

Figure 3 shows changes in JOA Score. There was a significant change of JOA score over time ($p=0.01$) and a significant group by time interaction ($p=0.02$). There was no statistically significant difference between groups ($p=0.24$). Changes of JOA score were -2.222 (95% CI, $-4.096 - -0.948$) points in the EA group and -0.802 (95% CI, $-0.764 - 0.364$) points in the TENS group. In summary, the JOA score improved in the EA group, while the TENS group showed no change.

Adverse events

Although one patient was withdrawn due to influenza, we judged that this had no relationship to the intervention. No adverse events were reported by the evaluator. The therapists reported some transient adverse events, for the EA group:

transient aggravation of LBP (1 case), discomfort due to press tack needles (1 case), pain on needle insertion (1 case) and small subcutaneous bleeding (10mm in diameter, 1 case); in the TENS group: transient aggravation of back pain (1 case), transient fatigue (1 case), itching with electrode (1 case). Seven patients in each group did not experience any adverse events.

Discussion

The results of the present trial showed a significant between-group difference in pain relief. Also, there was a statistically significant change over time and no significant group by time interaction. These results indicate that there was a significant reduction in pain relief in both groups, but the change in the EA group was greater than that in the TENS group. The EA group showed

improvement in JOA score, while the TENS group showed no change. These findings suggest that EA was more effective than TENS for short-term treatment of LBP in this study.

TENS is one of the most popular physical therapies in Japanese orthopaedic clinics. For patients with musculoskeletal problems, such as low back pain or hemiplegia following stroke, doctors and physiotherapists use TENS with various frequencies, including 1Hz. The frequency of 1Hz is commonly used in Japanese-style electroacupuncture, because intermittent stimulation, such as that at 1Hz, is considered to make patients feel more relaxed than stimulation at high frequency. Therefore, 1Hz TENS was selected as one of the usual treatments used in everyday practice.

There are some limitations to the present trial. First, the sample size is very small: this makes it difficult to generalise the results of the trial. Secondly, because we did not include any follow-up, it is impossible to discuss the long-term effect of EA and TENS. Thirdly, the number of treatment sessions was only four, and the treatment period was only two weeks: more sessions over a longer period might bring different results. Fourthly, we did not use a placebo control; therefore it is difficult to discuss the specific effect of EA. Considering these limitations, in a future trial, the ideal sample size should be calculated from the present results; the treatment period should be appropriate for chronic low back pain; and long-term follow-up should be performed.

Although preceding studies failed to show differences of efficacy between acupuncture and TENS,^{5,10,11} the present result demonstrates that acupuncture is more effective than TENS in treating LBP. The design of the present trial is similar to that by Sakai et al,⁵ except for the method of choosing treatment points. In the study by Sakai et al two points were selected bilaterally (i.e. four points in total) around the lumbar area. This is a simple technique and easy to reproduce. However, the number of points is too small, compared with standard acupuncture practice.⁴ It is therefore difficult to regard their acupuncture intervention as a standard practice.

Sufficient trial sensitivity may not necessarily be obtained by simple and reproducible

acupuncture procedures or intervention. Patel et al. noted that the trials employing individualised acupuncture treatment showed significantly better results compared with trials employing formulaic approaches.¹² Daily practice of acupuncture in the TCT clinic naturally contains the process of feedback through palpation, tenderness, muscle bands and so on.¹³ Further, Traditional Chinese Medical practitioners may perform pulse diagnosis or tongue diagnosis to refine treatment sensitivity. Similarly, individualised choice of points and stimulation is important in acupuncture RCTs.

Recently the major clinical research question on acupuncture seems to be either "Is there a specific effect of acupuncture beyond the placebo effect?" or "What benefit can patients get from acupuncture, regardless of the specific effect?" For the former question, adequate placebo control should be employed, and for the latter, active control, based on a realistic clinical situation, should be employed. The results of acupuncture RCTs using placebo or active control groups are still inconsistent.¹⁴ One of the main reason for this might be insufficient sensitivity of the trials. Individualised selection of points and dose based on standard practice may produce higher sensitivity. The sensitivity of interventions in acupuncture RCTs should be assessed prior to the trial.

Adequate interventions that have enough sensitivity and external validity should be employed for acupuncture RCTs. In the present preliminary study, although some placebo effect may be included, EA showed more effectiveness than TENS in short-term treatment of LBP. We suggest that acupuncture treatment methods in RCTs should be consistent with those in daily practice. We believe that more pragmatic RCTs such as the present trial are needed in order to assess relative clinical benefit in the field of healthcare.

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