SP Zhang 張世平
TTW Chiu 趙帶榮
SN Chiu 趙崇諾

Key Message

Electroacupuncture is a safe treatment for chronic neck pain. Nonetheless, one month after treatment, improvement of neck pain is similar to that in placebo-treated controls. This suggests that the efficacy may not be due to specific effect of the treatment procedure.

School of Chinese Medicine, Hong Kong Baptist University
SP Zhang
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University
TTW Chiu
Department of Mathematics, Hong Kong Baptist University
SN Chiu

HHSRF project number: 04060191

Principal applicant and corresponding author:
Dr SP Zhang
School of Chinese Medicine, Hong Kong Baptist University, Kowloon Tong, Hong Kong SAR, China
Tel: (852) 3411 2466
Fax: (852) 3411 2461
Email: spzhang@hkbu.edu.hk

Long-term efficacy of electroacupuncture for chronic neck pain: a randomised controlled trial

Introduction

Acupuncture may be more effective than placebo in producing immediate relief of neck pain, but controversies exist as to whether it has any long-term benefit. This study aimed to evaluate the long-term efficacy of electroacupuncture for chronic neck pain, and document any possible side effects.

Methods

This double-blind, randomised controlled trial was conducted from November 2006 to April 2009. Patients, practitioners, and the assessor were blind to the treatments. Adult subjects with chronic mechanical neck pain for ≥3 months were included. Patients with surgery to the neck, neurological deficits, a history of malignancy, congenital abnormality of the spine, systemic diseases, and those treated by acupuncture in the last 6 months were excluded.

A total of 206 Chinese patients (mean age, 45.8 years) with chronic neck pain (mean duration, 75.4 months) were randomised to receive electroacupuncture (n=103) or sham laser acupuncture (n=103) three times per week for 3 weeks. Randomisation took into account the age, gender, and degree of disability due to neck pain using computer software. An intention-to-treat analysis was performed.

Sterile acupuncture needles 25 to 40 mm long with a diameter of 0.25 to 0.30 mm were inserted into Hegu (LI4, x2), Houxi (SI3, x2), Feng Chi (GB20, x2), Jiangjing (GB21, x2), and Bailao and stimulated with an electroacupuncture machine for 45 minutes. Two additional points could be chosen from tender points or acupuncture points immediately near the tender points. Sham laser acupuncture was delivered via a mock laser pen that only emitted a red light. Neither the patients nor the practitioners were informed that the laser pen was inactivated. Each point was treated for 2 minutes, with the pen at a distance of 0.5 to 1 cm from the skin.

The primary outcome measure was the change in neck pain specific disability index, as measured by the Northwick Park Neck Pain Questionnaire (NPQ). Secondary outcome measures were (1) the change in maximum pain related to motion, regardless the direction of movement, on a 100-point pain scale, (2) quality of life assessment using SF-36 health survey, (3) use of medication for neck pain, and (4) sick leave for neck pain. Adverse effects and the credibility of real and sham treatments were assessed by a blind assessor before and after treatment.

Results

Of 103 patients in each group, 91 in the treatment group and 84 in the control group completed the treatment sessions. At the end of six months, 84 and 76 patients, respectively, had completed all follow-up assessments (Fig). About 70% of the patients were female. Over 90% of the patients had secondary school or higher levels of education, and about 40% of them worked in an office. The baseline characteristics of the two patient groups were similar (Table).

Reasons for dropout (no. of patients in the electroacupuncture and sham laser acupuncture groups):
1. No time (n=4+6)
2. Laser phobia (n=0+3)
3. Needle phobia (n=2+0)
4. Adverse effects:
    Neck pain (n=1+2)
    Headache (n=2+1)
    Dizziness (n=1+1)
    Bruise at acupoints (n=1+0)
5. Acute illness (n=0+1)
6. No improvement (n=1+5)

Recruited for initial assessment (n=270)

Included for randomisation (n=206)

Electroacupuncture group (n=103)

Sham laser acupuncture group (n=103)

Dropout (n=12)

Dropout (n=19)

Completed treatment session (n=91)

Completed treatment session (n=84)

Dropout (n=3)

Dropout (n=5)

Completed 1st month assessment (n=88)

Completed 1st month assessment (n=79)

Dropout (n=1)

Dropout (n=1)

Completed 3rd month assessment (n=87)

Completed 3rd month assessment (n=76)

Dropout (n=3)

Dropout (n=2)

Completed 6th month assessment (n=84) [81.6%]

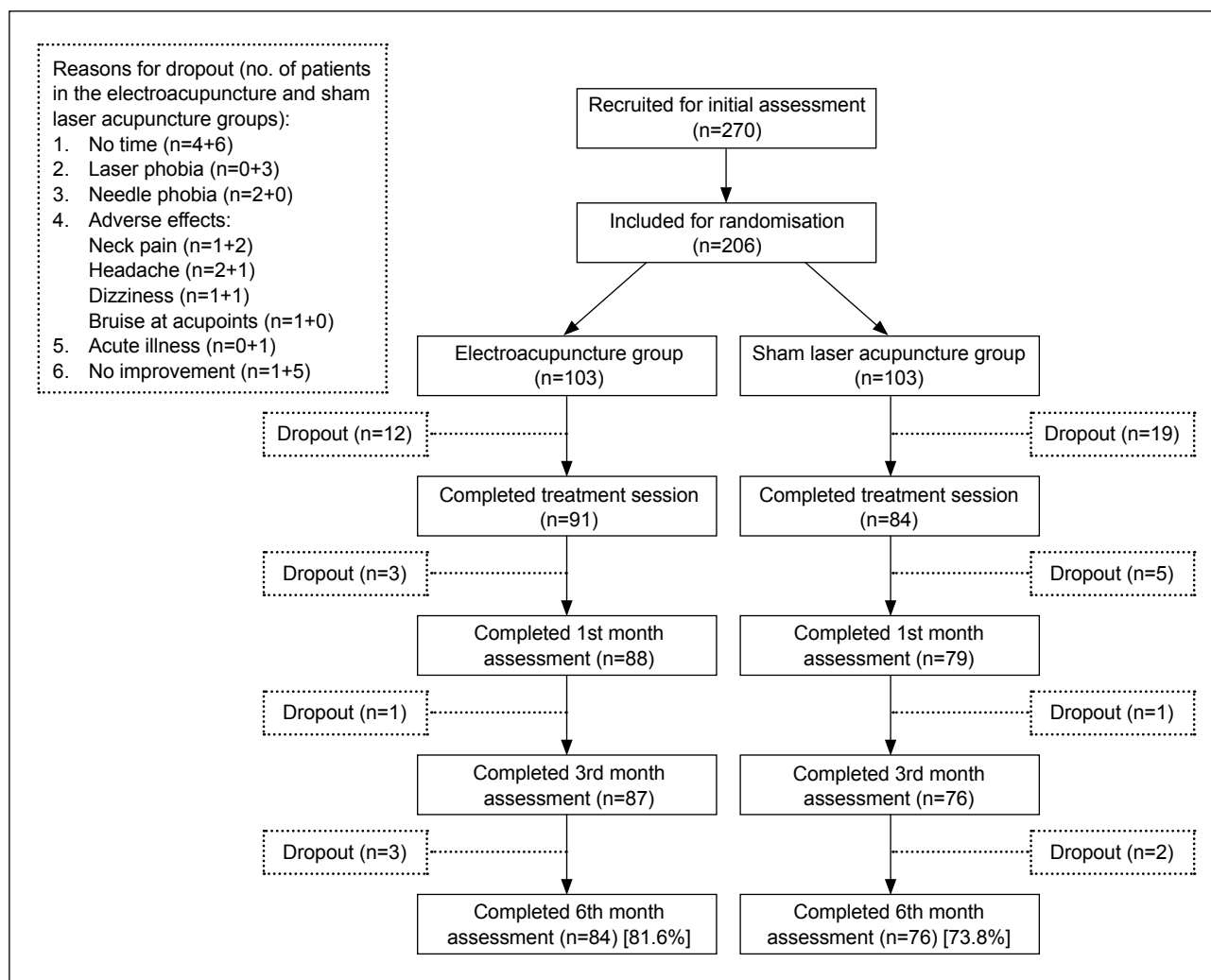Completed 6th month assessment (n=76) [73.8%]

Fig. Consort chart

Table. Changes in neck pain, disability, and quality of life after treatment

Predictors	Electroacupuncture (mean [95% CI])	P value for treatment effect	Sham-laser acupuncture (mean [95% CI])	P value for treatment effect	P value for between-group effect
Northwick Park Neck Pain Questionnaire score					
Pre-treatment	40.7 (38.5-42.9)		41.1 (38.7-43.5)		
1 month	35.1 (32.7-37.6)	0.013*	35.7 (32.8-38.6)	0.066	0.791
3 months	32.9 (30.3-35.4)	<0.001*	33.3 (30.1-36.5)	0.002*	0.664
6 months	33.5 (30.7-36.4)	<0.001*	34.3 (31.1-37.6)	0.009*	0.808
Numeric pain intensity scale score					
Pre-treatment	54.7 (50.9-58.4)		51.6 (47.6-55.7)		
1 month	50.8 (46.6-54.9)	0.835	46.9 (42.4-51.4)	0.807	0.813
3 months	46.6 (42.2-51.0)	0.046*	45.1 (40.5- 49.6)	0.234	0.617
6 months	46.8 (42.0-51.5)	0.054	43.6 (38.8-48.4)	0.076	0.813
SF-36 physical component score					
Pre-treatment	52.5 (51.5-53.4)		52.7 (51.9-53.6)		
1 month	52.6 (51.7-53.5)	1.000	53.0 (52.1-53.9)	1.000	0.396
3 months	52.8 (53.0-53.7)	1.000	53.3 (52.4-54.2)	1.000	0.982
6 months	53.0 (52.0-53.9)	1.000	53.2 (52.3-54.0)	1.000	0.559
SF-36 mental component score					
Pre-treatment	43.8 (42.9-44.8)		43.7 (42.6-44.8)		
1 month	45.3 (44.2-46.4)	0.182	44.4 (43.3-45.5)	1.000	0.389
3 months	45.9 (46.0 46.8)	0.015*	45.3 (44.2-46.4)	1.000	0.444
6 months	45.4 (44.5-46.3)	0.146	44.4 (43.4-45.4)	1.000	0.246

* P<0.05, ANOVA

In the treatment group, NPQ scores improved significantly at 1, 3, and 6 months, compared to the baseline value (ANOVA with Bonferroni post-hoc test). Significant improvement was also noted in the bodily pain score of the SF-36 at 1 month, the numeric pain intensity scale score, bodily pain score, vitality, and mental component score and total score of the SF-36 at 3 months, and the bodily pain score of the SF-36 at 6 months. In the control group, NPQ scores improved significantly at 3 and 6 months, as did the bodily pain score of the SF-36 at 1, 3, and 6 months. More items yielded improvements in the treatment than control group (Table).

Using multiple analysis of covariance after controlling for confounding variables (gender, age, duration of pain before treatment, and job nature), the two groups did not differ significantly (P=0.975). All confounding variables had no significant effect. Whether the treatment effect (β5) was significant was determined in the following model: $y = \alpha + \beta1$ (gender) $+ \beta2$ (age) $+ \beta3$ (pain duration) $+ \beta4$ (job nature) $+ \beta5$ (group) $+ \varepsilon$, where y was a vector containing all outcome measures (excluding the reductions in the number of sick leaves and the SF36 total scores) of a respondent and ε a normally distributed random vector representing random errors. The parameters α, $\beta1$, $\beta2$, $\beta3$, $\beta4$, and $\beta5$ were unknown vectors. The reduction in the number of sick leaves was excluded because such a reduction is an integer and the normally distributed random error was not applicable. The SF36 total score was excluded because it is just the sum of the physical and mental component scores.

The credibility of the test and control treatments was assessed using the Borkovec and Nau scale.[1] At the beginning of the treatment, subjects gave scores of 4 to 4.9 (out of a 6-point scale) for both treatments, indicating good credibility. There was no significant within-group difference before and after treatments, suggesting that the treatment process did not alter the credibility rating significantly. There was a significant between-group difference, indicating that electroacupuncture was perceived as a more credible treatment than laser acupuncture. Nevertheless, concealment of electroacupuncture as the real treatment was successful, as the number of subjects who correctly guessed the nature of treatment received was not significantly different in the two groups (P=0.108). All practitioners believed that laser acupuncture was an active treatment, although they believed that electroacupuncture would be more effective.

Respectively in the electroacupuncture and sham laser acupuncture groups, adverse reactions reported were increased neck pain (n=1+2), headache (n=2+1), dizziness after treatment (n=1+1), bruise at acupoints (n=2+0), pain at acupoint after treatment (n=1+0), chest discomfort after treatment (n=1+0), itching palm after treatment (n=0+1), warm-feeling at the back after treatment (n=0+1). No severe adverse reaction was noted.

Discussion

Compared to sham laser acupuncture, no long-term benefit could be demonstrated for electroacupuncture, although both groups showed small but significant improvements. Whether such improvement was due to spontaneous remission of the disease or the treatment is unknown. The masking of controls was successful for both patients and practitioners. The electroacupuncture treatment was well tolerated and resulted in few adverse effects. The improvements in NPS and numeric pain intensity scale scores in both groups were small (<20%). In chronic pain patients, ≥30% difference is considered clinically significant.[2] Therefore, neither group had clinically significant improvement after treatment.

Several factors may contribute to the improvement of symptoms. First, patient's experience of the treatment process, including patient participation and practitioner attention could have a positive psychological or placebo effect. Second, both treatments might have physiological effects. Electroacupuncture is known to evoke physiological reactions,[3] but physiological reactions to shining a red-light on acupoints has never been evaluated. Sham laser acupuncture had been demonstrated to be inferior to electroacupuncture.[4] Sham laser acupuncture might nevertheless have a small physiological effect equal to electroacupuncture, as it might activate similar parts of the brain involved in pain modulation.[3] Nevertheless, the magnitude of the present effects from both treatment was small. Third, spontaneous resolution of the condition may also account for the improvements.

One limitation of this study was that there was no second control arm, in which participants received no treatment. Thus we were not able to assess the efficacy of the treatment procedure compared to spontaneous remission. In a review of 14 clinical trials of acupuncture for neck pain, short-term effect was demonstrated, but long-term effect was uncertain.[5] Compared to previous studies, our study recruited larger samples and used more stringent methodology, such as concealment of the treatment nature from patients and practitioners, and use of software to ensure a balance of baseline features of the two groups. Our study confirmed that for chronic neck pain there is little, if any, long-term efficacy from electroacupuncture. Owing to the low external validity, our findings may not be generalised to other acupuncture practices, such as manual acupuncture.[6] Our findings have certain implications for clinical research. We initially chose to study the effects of electroacupuncture because the procedures could be standardised and easily replicated in clinical practice. However, the standardisation of procedures also meant that there was little flexibility in the choice of acupuncture regimens, which often change in clinical practices when a patient fails to respond to a particular regimen. For example, a Chinese medicine practitioner may start with electroacupuncture for a patient with chronic mechanical neck pain, but change to manual acupuncture plus moxibustion if the patient does not

respond well. Such flexibility in the choice of regimens is part of the individualised treatment principle in acupuncture practice. We therefore suggest that future clinical research with acupuncture should try to simulate clinical practice as far as possible, so as to improve external validity. Although electroacupuncture for chronic neck pain is safe, it has limited efficacy. Practitioners should be prepared to abandon the treatment if the patient does not respond well.

Acknowledgements

References

1. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. J Behav Ther Exp Psychiatry 1972;3:257-60.
2. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149-58.
3. Lewith GT, White PJ, Pariente J. Investigating acupuncture using brain imaging techniques: the current state of play. Evid Based Complement Alternat Med 2005;2:315-9.
4. Irnich D, Behrens N, Molzen H, et al. Randomised trial of acupuncture compared with conventional massage and "sham" laser acupuncture for treatment of chronic neck pain. BMJ 2001;322:1574-8.
5. Fu LM, Li JT, Wu WS. Randomized controlled trials of acupuncture for neck pain: systematic review and meta-analysis. J Altern Complement Med 2009;15:133-45.
6. Macpherson H. Pragmatic clinical trials. Complement Ther Med 2004;12:136-40.