Diseases of the Musculoskeletal and Connective Tissue

Reference

Sakai T, Tsutani K, Tsukayama H, et al. Multi-center randomized controlled trial of acupuncture with electric stimulation and acupuncture-like transcutaneous electrical nerve stimulation for lumbago. *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 2001; 51(2): 175–84 (in Japanese with English abstract). Ichushi Web ID: 2001280876

1. Objectives

To evaluate the efficacy and safety of low-frequency electro-acupuncture and transcutaneous electrical nerve stimulation (TENS) for low back pain.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Four medical facilities in Japan (Meiji University of Oriental Medicine Hospital [current Meiji University of Integrative Medicine], Kyoto; Outpatient Clinics, Kansai College of Oriental Medicine [current Kansai University of Health Sciences], Osaka; Tsukuba College of Technology Clinic, Ibaraki; and Department of Medicine and Physical Therapy, Faculty of Medicine, University of Tokyo, Tokyo).

4. Participants

A total of 70 male and female patients aged 20 years or older who had low back pain without leg pain and provided consent.

5. Intervention

Arm 1: Low-frequency electro-acupuncture therapy group. Two points each for the left and right sides were selected from reactive points (taut, tender, or indurated) on the BL23(腎俞), BL25 (大腸俞), and BL52 (志室) acupuncture points, and electro-acupuncture was applied at a frequency of 1 Hz for 15 minutes using stainless steel needles (0.24×60 mm). Treatment was administered 5 times during a 2-week period (n=32).

Arm 2: TENS group. Sites, frequency, intensity, and duration of stimulation and frequency and number of treatment sessions were the same as those in Arm 1 (n=36).

There was a 1-week run-in period (patches were applied), during which 2 patients dropped out. Of the rest of 68, 4 patients dropped out of the study (1 in Arm 1, 3 in Arm 2).

6. Main outcome measures

Change in pain intensity rated on a 5-point visual analogue scale (VAS) and using the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score).

7. Main results

Among background factors, gender, history of acupuncture, and history of TENS were different between the two arms. There was no significant between-arm difference in pain relief and JOA score.

8. Conclusions

Low-frequency electro-acupuncture and TENS have similar efficacy for low back pain.

9. From acupuncture and moxibustion medicine perspective

None.

10. Safety assessment in the article

In Arm 2, two patients complained of itching resulting from the application of electrodes.

11. Abstractor's comments

In this ambitious RCT, the protocol, which is central to conducting a clinical trial, was developed over an extended period of time and the efficacy of acupuncture for low back pain, an important disorder in clinical practice of acupuncture and moxibustion, was evaluated in a multicenter setting. This study is regarded as an exploratory phase 2 trial, aiming to collect basic data for a phase 3 trial. Regrettably, TENS was used as the control treatment, but "no treatment" would have been a more desirable control. The study provides investigators who are planning RCTs with a lot of useful information, including issues concerning recruitment of subjects and selection of outcome measures.

12. Abstractor and date

Takahashi N, 9 February 2011.