9. Cardiovascular Diseases

Reference

Kawase Y, Ishigami T, Hori S, et al. Effectiveness of the Zusanli (ST36) point for hypertension in acupuncture -Controlled clinical trials using the envelope method- *Zen Nihon Shinkyu Gakkai Zasshi* (*Journal of the Japan Society of Acupuncture and Moxibustion*) 2000; 50: 185–89 (in Japanese with English abstract). Ichushi Web ID: 2000218637

1. Objectives

To evaluate the depressor effect of acupuncture at the ST36 (足三里) acupuncture point.

2. Design

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

3. Setting

Multicenter clinical trial in 10 clinics in Japan.

4. Participants

Twenty four patients whose all three measurements of blood pressure met the criteria for hypertension, defined by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (USA).

5. Intervention

Arm 1: Taikyoku therapy (太極療法, holistic approach to acupuncture and moxibustion treatment)+hyochiho (標治法, local or symptomatic treatment)+acupuncture at the ST36 (足三里) acupuncture point (n=12).

Arm 2: Taikyoku therapy+hyochiho (n=12).

Treatments were administered at least once weekly and at least 8 times during the study period.

Data for only 14 of the 24 participants with a diastolic pressure of 90 mmHg or higher and a systolic pressure of 140 mmHg or higher were reported.

6. Main outcome measures

Diastolic and systolic blood pressures.

7. Main results

Intragroup comparison revealed significant changes in systolic pressure only in Arm 2 (P<0.01, ANOVA). Diastolic pressure changed significantly in both Arms 1 and 2 (P<0.01). There were, however, no significant between-arm differences.

8. Conclusions

The ST36 (足三里) acupuncture point does not have a depressor effect in hypertensive patients.

9. From acupuncture and moxibustion medicine perspective

Single acupuncture at the ST36 (足三里), in addition to taikyoku therapy and hyochiho, was administered to treat hypertension, but no clinical effect was identified.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This multicenter clinical trial in 10 acupuncture and moxibustion clinics was a meaningful attempt. It is, however, problematic that only 24 patients were enrolled and assigned treatment at each site. In addition, considering that the objective of the study was to evaluate the depressor effect of acupuncture at the ST36 ($\mathcal{R} \equiv \mathbb{H}$) acupuncture point, there is strong doubt about the adequacy of the study design: stimulation of 13 acupuncture points, as taikyoku therapy, plus hyochiho were administered in both arms, and then single needling technique was applied at the ST36 ($\mathcal{R} \equiv \mathbb{H}$) acupuncture point only in Arm 1. Results showed slight, but not significant, differences in reductions in blood pressure between the two Arms. The possibility of type II error cannot be ruled out because of the small number of patients included. It is also regrettable that outcomes of 10 out of 24 patients included were not described and no measurements at 3 months were reported. This article brings into question the design of clinical trials conducted in acupuncture and moxibustion clinics in Japan. Suggestions to resolve this issue are needed.

12. Abstractor and date

Kawakita K, 9 September 2011.