9. Cardiovascular Diseases

Reference

Sasaki J, Matsunaga A, Kusuda M, et al. Efficacy of daisaikoto and chotosan in patients with essential hypertension. *Rinsho to Kenkyu* (*Japanese Journal of Clinical and Experimental Medicine*) 1993; 70: 1965-75 (in Japanese). Ichushi Web ID: 1994042619

1. Objectives

To evaluate the efficacy and safety of daisaikoto (大柴胡湯) and chotosan (釣藤散) in patients with essential hypertension.

2. Design

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

3. Setting

Five hospitals (1 university hospital and 4 clinics), Japan.

4. Participants

A total of 94 patients who met the following 4 criteria: 1) essential hypertension with unidentified complaints, 2) inadequate control of hypertension by other antihypertensive agents, 3) mild hypertension, and 4) judged to be appropriate for the study. Of these, 83 patients were included for analysis.

5. Intervention

Jitsu-sho Arm 1: thirty patients with *jitsu-sho* (実証, excess pattern). Tsumura Daisaikoto (大柴胡湯) Extract Granules (TJ-8) 2.5 g t.i.d. for 8 weeks (n=14); *jitsu-sho* arm 2: no administration (n=15).

Kyo-sho Arm 1:Sixty-two patients with *kyo-sho* (虚証, deficiency pattern).Tsumura Chotosan (釣藤散) Extract Granules (TJ-47) 2.5 g t.i.d. for 8 weeks (n=24); *kyo-sho* arm 2: no administration (n=30).

6. Main outcome measures

Blood pressure (BP). Pulse rate. Subjective symptoms assessed in 3 grades (improved, no change, or worse); headache, heaviness of the head, dizziness, shoulder stiffness, palpitation, hot flashes, irritation, tinnitus, insomnia, anxiety/restlessness, cold or hot feelings in the limbs, numbness in the limbs, loss of appetite, constipation, diarrhea, nausea, dry mouth, eye fatigue, and lassitude. Global improvement. The results of laboratory tests.

7. Main results

Diastolic BP in *jitsu-sho* arm 1 and BP in *kyo-sho* arm 1 were significantly decreased in the treatment group when compared to the untreated group after 8 weeks. Tinnitus was significantly improved ($P<0.05$) and global improvement was better in chotosan-treated arm (*kyo-sho arm 1*). The results of laboratory tests remained within normal limits.

8. Conclusions

In *kyo-sho* patients, chotosan has a significant antihypertensive effect.

9. From Kampo medicine perspective

In this study, patients were grouped into *jitsu-sho* and *kyo-sho* using a questionnaire, and were treated with Kampo drugs appropriate for their *sho* (証, pattern).

10. Safety assessment in the article

Fifteen patients in arm 1 and 26 patients in arm 2 were assessed. In the daisaikoto treatment group, 1 patient experienced watery diarrhea and withdrew from the study. In the chotosan treatment group, 1 patient discontinued treatment because of abdominal discomfort and bloating and withdrew from the study.

11. Abstractor's comments

This is an important report on the Kampo treatment of hypertensive patients based on body constitution (*sho*). In this study, a significant antihypertensive effect of chotosan in *kyo-sho* patients was observed. On the other hand, this paper did not elucidate the hypotensive effect of daisaikoto in *jitsu-sho* patients and was therefore consistent with other papers reporting that orengedokuto (黄連解毒湯) used for *jitsu-sho* or *chukan-sho* has no direct hypotensive effect ("Arakawa K, Saruta T, Abe K, et al. Double-blind placebo-controlled trial of TSUMURA Orengedokuto (TJ-15) for the treatment of accessory symptoms of hypertension*. *Rinsho to Kenkyu* (*Japanese Journal of Clinical and Experimental Study*) 2003; 80: 354-72 (in Japanese)" Ichushi Web ID: 2003184342 MOL, MOL-Lib). It might be that blood pressure is more closely associated with symptoms in *kyo-syo* patients. It would be interesting to know whether the effects can still be observed when the *sho* of the patients is not considered. Efficacy of chotosan for tinnitus has been previously reported, and this study confirmed this effect in *kyo-sho* patients.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010.