

9. Cardiovascular disease

Reference

Kaneko H, Nakanishi K, Murakami A, et al. Clinical evaluation of the effect of Ohrengedoku-Toh and Ohrengedoku-Toh-Red Ginseng mixture on chronic cardiovascular disorders in middle and aged patients. *The Ginseng Review* 1991; 12: 89-93 (in Japanese with English abstract).

1. Objectives

To evaluate the efficacy and safety of orengedokuto (黄連解毒湯) plus red ginseng combination therapy for relieving symptoms associated with hypertension.

2. Design

Double-blind randomized controlled trial (DB-RCT).

3. Setting

Five clinics, Japan.

4. Participants

A total of 40 out-patients with stable symptoms were recruited, 29 of whom were included for analysis (hypertension, n=14; atherosclerotic disease, n=6; ischemic heart disease, n=4; others, n=5).

5. Intervention

Arm 1: Kotaro Orengedokuto (黄連解毒湯) Extract Granules 2.5 g t.i.d. between meals (n=15).

Arm 2: Kotaro Orengedokuto (黄連解毒湯) Extract Granules 2.0 g t.i.d. plus CHEONG-KWAN-JANG kojimatsu powder (正官庄紅參末) 1.0 g t.i.d. between meals (n=14).

6. Main outcome measures

Subjective symptoms (insomnia, numbness of the limb, palpitation, tinnitus, vertigo, orthostatic syncope, stiff shoulder, headache/heaviness of head, and amnesia), overall improvement, and general effect were evaluated. Blood pressure, pressure rate product (PRP: blood pressure × heart rate), echocardiogram (resting coronary flow velocity [RFV] and left ventricular [LV] mass) were also determined.

7. Main results

Only numbness of the limbs was significantly improved in arm 1, whereas vertigo, stiff shoulder, headache/heaviness of head and general effect were significantly improved in arm 2. When subjects in both arms were further subgrouped according to *jitsu-sho* (実証, excess pattern) and *kyo-syo* (虚証, deficiency pattern), in arm 1, improved items were observed only in subjects with *kyo-sho*. In arm 2, improvement in shoulder stiffness and vertigo was found in *jitsu-syo*-type patients, and headache improved in *kyo-syo*-type patients. Improved cardiovascular hemodynamics (decreased blood pressure, increased RFV, decreased LV mass, and lower PRP) were observed in arm 2.

8. Conclusions

When compared with single administration of orengedokuto, combination therapy with kojimatsu effectively improved subjective symptoms as well as cardiovascular hemodynamics.

9. From Kampo medicine perspective

Subjects in both arms were further classified on the basis of *jitsu-sho* and *kyo-syo* for evaluation, which demonstrated more efficacy in arm 2 regardless of *sho*.

10. Safety assessment in the article

None.

11. Abstractor's comments

The result here is surprising in that even after short-term (12-week) administration, combination therapy with kojimatsu was more effective than administration of orengedokuto alone. Orengedokuto is generally used for subjects with intermediate- or *jitsu-sho*; however, the result here demonstrating more efficacy in *kyo-syo*-type patients than in *jitsu-sho*-type patients should serve as a useful reference. Combination of the two drugs increased the effectiveness even in patients with *jitsu-sho*, suggesting its usefulness (suitability for a wider range of patients) and efficacy (improvement in cardiovascular hemodynamics). Further studies with a larger sample size are awaited.

12. Abstractor and date

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