Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

9. Cardiovascular diseases

References

Narumi J, Kohsaka S, Miyazawa S, et al. Evaluation of the Kampo monotreatment for hypertensive patients using ambulatory blood pressure monitoring. *Wakan Iyakugaku Zasshi (Journal of Traditional Medicines)* 1994; 11: 282-3 (in Japanese).

Narumi J, Kohsaka S, Miyazawa S, et al. Evaluation of the Kampo monotreatment for hypertensive patients using ambulatory blood pressure monitoring *. *Kampo Shinryo* 1996; 15: 34-5 (in Japanese).

1. Objectives

To evaluate the efficacy of chotosan (釣藤散) and orengedokuto (黄連解毒湯) for hypertension using ambulatory blood pressure monitoring.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Eight hypertensive patients who visited the hospital for the first time.

5. Intervention

Arm 1: Tsumura Chotosan (釣藤散) Extract Granules (TJ-47) 7.5 g/day (n=3).

Arm 2: Tsumura Orengedokuto (黄連解毒湯) Extract Granules (TJ-15) 7.5 g/day (n=5).

The period of administration was 15–265 days.

6. Main outcome measures

Blood pressure (BP) was measured using an ambulatory blood pressure monitor (ABPM) before and after treatment, and the following BP values were determined: 1) the 24-hour average systolic BP (sBP) and diastolic BP (dBP), 2) the average daytime sBP and dBP, 3) percentage of ambulatory dBPs more than 90 mm Hg during 24 hours (diastolic pressure load), and 4) BP values analyzed by a cosinor method. Hypertensive patients with or without accessory symptoms were separately assessed.

7. Main results

1) A 24-hour antihypertensive effect on sBP was observed in 3 patients in arm 2, and a 24-hour antihypertensive effect on dBP was observed in 1 patient in arm 1. 2) Daytime sBP decreased in 1 patient in arm 1 and 3 patients in arm 2, and daytime dBP decreased in 1 patient in arm 1 and 1 patient in arm 2. 3) Reduction in diastolic pressure load was noted in 2 patients in arm 1 and 1 patient in arm 2. 4) Cosinor

analysis revealed efficacy in 1 patient in arm 1 and 2 patients in arm 2. In patients with accessory symptoms, headache and heaviness of the head improved in 1 patient in arm 1,

In patients with accessory symptoms, headache and heaviness of the head improved in 1 patient in arm 1, headache and shoulder stiffness improved in 1 patient in arm 1, but no indices of hypertension for these patients was affected. Lightheadedness in 1 patient in arm 2 was accompanied by decrease in BP.

8. Conclusions

Kampo monotreatment has a satisfactory hypotensive effect in some cases.

9. From Kampo medicine perspective

It is noted that in two patients with *sho* (証, pattern) for chotosan, treatment was effective (all indices) for 1 patient but not for the other. Also in a patient with *sho* for orengeokuto, no effect was observed.

10. Safety assessment in the article

In the "result" and "discussion" sections of the related article, it is noted that the Kampo diagnosis of "*sho* (記, pattern)" may not be associated with a hypotensive effect of Kampo treatment, which may not be observed even when *sho* is compatible with the Kampo prescription.

11. Abstractor's comments

Despite the small number of the subjects, this is an important report that evaluates (using ABPM) the hypotensive effect of Kampo drugs. The results of many multicenter trials of orengedokuto for treatment of hypertension suggest its efficacy for accessory symptoms but not for high BP. However, I have the clinical impression that orengedokuto is effective in some cases, and these data support that impression. Analysis found no association between the accessory symptoms and *sho*. How goals *sho* for use of Kampo drugs are set (e.g., trial and error) should be further investigated.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010, 31 December 2013.