18. Symptoms and Signs

References

Seki H, Tateyama M, Sahara M, et al. Pain-relieving effect of goshuyuto on chronic headache: comparison with keishininjinto (with randomization using the sealed-envelope method)*. *Shinryo to Shinyaku* (*Medical Consultation & New Remedies*) 1991; 28: 573–6 (in Japanese). Ichushi Web ID: 1992103222

Seki H, Okita N, Takase S, et al. Pain-relieving effect of goshuyuto on chronic headache: comparison with keishininjinto (with randomization carried out using the sealed-envelope method)*. *Pharma Medica* 1993; 11: 288–91 (in Japanese). Ichushi Web ID: 1994170314

1. Objectives

To evaluate the efficacy and safety of goshuyuto (呉茱萸湯) for relieving chronic headache using keishininjinto (桂枝人参湯) as a control.

2. Design

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

3. Setting

The department of neurology of one hospital, Japan.

4. Participants

Eighty-eight patients with chronic headache.

5. Intervention

Arm 1: oral administration of goshuyuto (呉茱萸湯) (manufacturer unknown) 2.5 g t.i.d. for 4 weeks (n=44).

Arm 2: oral administration of keishininjinto (桂枝人参湯) (manufacturer unknown) 2.5 g t.i.d. for 4 weeks (n=44).

6. Main outcome measures

Headache severity rated on a 4-point scale.

7. Main results

Headache severity was at least moderately improved in 56.8% and 38.6% of patients and at least slightly improved in 79.5% and 61.4% of patients in the goshuyuto (呉茱萸湯) group and keishininjinto (桂枝人参湯) group, respectively.

8. Conclusions

The effect of goshuyuto on chronic headache is comparable to that of keishininjinto.

9. From Kampo medicine perspective

Goshuyuto was expected to be effective in patients prone to obesity and constipation and with cold limbs, whereas keishininjinto was expected to be effective in lean patients prone to loose stool.

10. Safety assessment in the article

Mild increase in gamma-glutamyltranspeptidase (γ-GTP), glutamic oxaloacetic transaminase (GOT), and glutamic pyruvic transaminase (GPT) or prickly heat rash was noted in 3 patients in arm 1.

11. Abstractor's comments

This clinical study investigated the efficacy of goshuyuto for chronic headache using keishininjinto as a control and is excellent because it reviewed the *sho* (証, pattern) of the responsive group with the intention of elucidating the pathology of chronic headache according to Kampo concepts. Unfortunately, the results were not statistically significant. The failure to demonstrate a significant between-arm difference may be due to the use of only one measure of headache severity. Evaluating headache frequency, time to resolution, and frequency of use of as-needed drugs might have revealed differences in the efficacy of goshuyuto and keishininjinto. The names of the drug combinations and drug manufacturers should also have been specified. In addition, the *sho* (証, pattern) should have been used to identify the indications for goshuyuto and keishininjinto rather than to compare the indications for these medicines. Nevertheless, this clinical study is valuable because it considered the difficulty of using a placebo in patients with clinical complaints. The article by Seki et al (1991) was the interim report for this study.

12. Abstractor and date

Goto H, 14 September 2008, 1 June 2010, 31 December 2013.