18. Symptoms and Signs

References

Odaguchi H, Hanawa Y. Complementary alternative medicine in headache treatment*. *Igaku no Ayumi* (*Journal of Clinical and Experimental Medicine*) 2005; 215: 1137-40 (in Japanese) MOL, MOL-Lib

Odaguchi H, Wakasugi A, Ito H, et al. The efficacy of goshuyuto, a typical Kampo (Japanese herbal medicine) formula, in preventing episodes of headache. *Current Medical Research and Opinion* 2006; 22: 1587-97. CENTRAL ID: CN-00571314, Pubmed ID: 16870083

1. Objectives

To evaluate the efficacy of goshuyuto (呉茱萸湯) for relief of chronic headache and to evaluate the associated adverse drug reactions.

2. Design

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

3. Setting

Three university-associated outpatient headache clinics, Japan.

4. Participants

Fifty-three patients with chronic headache that responded to goshuyuto orally administered for 4 weeks.

5. Intervention

Arm 1: oral administration of 7.5 g/day of TSUMURA Goshuyuto (呉茱萸湯) Extract Granules for 12 weeks (n=28).

Arm 2: oral administration of the same dose of placebo granules indistinguishable in appearance, taste, and odor from goshuyuto for 12 weeks (n=25).

6. Main outcome measures

Headache severity, headache frequency, and severity of cold, menstrual cramps, and shoulder stiffness evaluated in all participants.

Surface temperature of fingers and toes, skin blood flow, deep body temperature, brain and femoral oxygen saturation, rigidity of the trapezius muscle, and blood serotonin concentration evaluated in some participants.

7. Main results

After a 12-week treatment, the number of days with headache was significantly decreased from baseline by 2.6 in arm 1 but remained unchanged in arm 2 (decreased by 0.3), showing significantly greater improvement in arm 1 than in arm 2. In addition, the number of doses of an analgesic taken was significantly decreased from baseline by 2.2 in arm 1 but remained unchanged (decreased by 1.4) in arm 2, indicating no between-arm difference. Comparison limited to migraine disclosed the same trend. There were no significant changes in the other parameters in both arms.

8. Conclusions

Goshuyuto decreases the frequency of headache episodes in patients with chronic headache, thereby reducing the number of analgesic doses.

9. From Kampo medicine perspective

This study considers *sho*, since its first stage involved selection of only goshuyuto-responders as "*sho* for goshuyuto," and these were enrolled in a double-blind, randomized controlled trial at the second stage.

10. Safety assessment in the article

No adverse drug reactions occurred except for increases in ALT, AST and γ–GTP in 1 patient receiving goshuyuto. These reactions persisted 3 months after drug discontinuation, suggesting possible development of fatty liver.

11. Abstractor's comments

In this study, goshuyuto was administered to 91 patients with chronic headache at its first stage to select responders (n=53) for a double-blind, randomized controlled trial at its second stage. Thus, it may be a groundbreaking study in that it focused on "*sho*." Besides headache, menstrual cramps and shoulder stiffness also tended to be improved by treatment with goshuyuto, warranting investigation with a larger sample size to clarify "goshuyuto-*sho*." More clinical studies in oriental medicine such as the present study are expected in the future.

12. Abstractor and date

Goto H, 1 April 2008, 1 June 2010, 31 December 2013.