

## 6. Nervous System Diseases (including Alzheimer's Disease)

**Reference**

Maruyama T. Goshuyuto versus lomerizine hydrochloride in the prophylactic treatment of migraine headaches: an open crossover trial.. *Itami to Kampo (Pain and Kampo Medicine)* 2006; 16: 30-9 (in Japanese with English abstract). Ichushi Web ID: 2006303125

**1. Objectives**

To evaluate the efficacy and safety of goshuyuto (呉茱萸湯) for treatment of migraine.

**2. Design**

A crossover randomized controlled trial (RCT-crossover).

**3. Setting**

No description of the setting is available; the authors belong to the Department of General Medicine, Iida Municipal Hospital, Japan.

**4. Participants**

Fourteen patients with at least a 1-year history of migraine and suffering a mean of 3 or more migraine attack events monthly.

**5. Intervention**

Arm 1: Oral administration of lomerizine hydrochloride 5 mg 5 mg b.i.d. for 28 days, followed by a wash-out period of two weeks, and then oral administration of TSUMURA Goshuyuto (呉茱萸湯) Extract Granules 2.5 g t.i.d. for 28 days (n=7).

Arm 2: Oral administration of TSUMURA Goshuyuto (呉茱萸湯) Extract Granules 2.5 g t.i.d. for 28 days, followed by a wash-out period of two weeks, and then oral administration of lomerizine hydrochloride 5 mg b.i.d. for 28 days (n=7).

Oral triptans to treat migraine attacks were allowed.

**6. Main outcome measures**

Frequency of migraine attacks, visual analogue scale (VAS) score, number of triptan oral tablets used, response to a triptan (time to relieve attacks), evaluated in the pretreatment period (28 days), course 1 (28 days), withdrawal period (14 days), course 2 (28 days), and final period (28 days).

**7. Main results**

Differences in measures of drug efficacy (i.e., frequency of migraine attacks, VAS peak value, and number of triptan oral tablets used) were greater in goshuyuto group than in lomerizine hydrochloride group.

**8. Conclusions**

Goshuyuto is more effective for migraine attacks than lomerizine hydrochloride.

**9. From Kampo medicine perspective**

As indications of goshuyuto, the following *shoes* were identified: *genchimyaku* (弦遲脈, string-like, slow pulse), *katsuhakutai* (滑白苔, slippery white tongue coating), *shinsuion* (振水音, splashing sounds in the stomach), *shinkahikou* (心下痞鞭, stiffness and rigidity below the heart), *shishikanrei* (四肢厥冷, reversal cold of the limbs) in 71.4, 57.1, 64.3, 85.7, and 100% of patients.

**10. Safety assessment in the article**

While 2 patients receiving lomerizine hydrochloride experienced sleepiness, none receiving goshuyuto experienced any adverse drug reactions.

**11. Abstractor's comments**

This excellent clinical study investigated the effect of goshuyuto on migraine using lomerizine hydrochloride as the control and demonstrated that it prevented migraine attacks. However, the author stated in the discussion of his paper that lomerizine hydrochloride used as the control was weaker than reported in previous clinical research. Therefore, it would be necessary to determine whether migraine was correctly diagnosed in participants and whether response to previous oral treatment with lomerizine hydrochloride was poor. Furthermore, in arm 2, goshuyuto was received in course 1, and the frequency and severity of migraine attack had not returned to baseline levels by the start of lomerizine in course 2, suggesting that the pace of withdrawal was too rapid. This may explain the stronger effect of goshuyuto in arm 1 (patients who received goshuyuto in course 2). Moreover, compliance with goshuyuto treatment (74%) was significantly lower than compliance with lomerizine hydrochloride treatment (93%), warranting improvement in future compliance. Nevertheless, this research demonstrated that goshuyuto prevented migraine, and further investigation of its efficacy is expected with various prescriptions.

**12. Abstractor and date**

Goto H, 17 November 2008, 1 June 2010, 31 December 2013.