

13. Diseases of the Musculoskeletal System and Connective Tissue**Reference**

Nakamura T, Souza ACA, Ouchi Y, et al. Effects of goshajinkigan on lumbago*. *Dai 4 Kai Tokyo Naika Kampo Kenkyukai Koen Naiyo Shu (Proceedings of the 4th Meeting of the Tokyo Society for Internal Kampo Medicine)* 1989; 4: 24–9 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) in comparison with that of tiaramide hydrochloride for lumbago in the elderly.

2. Design

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

3. Setting

One facility (Department of Geriatric Medicine, University of Tokyo Hospital), Japan.

4. Participants

Twenty-five elderly patients with lumbago visiting the above facility (3 males and 22 females; 60–87 years old).

5. Intervention

Arm 1: goshajinkigan (牛車腎気丸) (manufacturer, not specified) 2.5 g t.i.d. before meals (n=11).

Arm 2: tiaramide hydrochloride 100 mg t.i.d. after meals (n=7).

Arm 3: goshajinkigan (牛車腎気丸) (manufacturer, not specified) 2.5 g t.i.d. before meals + tiaramide hydrochloride 100 mg t.i.d. after meals (n=7).

Treatment duration: 4 weeks.

6. Main outcome measures

Improvement rating of subjective symptoms including lumbago evaluated on a 4-point scale.

7. Main results

Goshajinkigan was effective for lumbar numbness and stiffness, while tiaramide hydrochloride was effective for lumbago and irradiating pain at rest (no test for significance of the difference). Goshajinkigan had an equivalent or greater effect than tiaramide hydrochloride on reducing pain while rising to a standing position from sitting, anteflexion, retroflexion, and rolling over (no test for significance of the difference). Severity of lumbago was improved in all groups, although there was no significant among-arm difference in this improvement.

8. Conclusions

In the elderly with lumbago, goshajinkigan is equally or more effective than tiaramide hydrochloride for pain during movement but not effective for pain at rest.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse reactions occurred in 2 patients receiving goshajinkigan (discomfort [n=1]; administration discontinued] and anorexia [n=1]) and 1 patient receiving tiaramide hydrochloride (anorexia). However, anorexia disappeared during continued administration.

11. Abstractor's comments

Goshajinkigan has traditionally been reported to be effective in the elderly for lumbago, which has a pathology of *jinyokyo* (腎陽虚, kidney yang deficiency). This study demonstrated that goshajinkigan and a Western medicine with established efficacy have comparable efficacy. The small sample size regrettably prevented sufficient group comparison in this study. Future case series are expected to include investigation of the influence of *sho* (証, pattern).

12. Abstractor and date

Ushiroyama T, 16 August 2008, 1 June 2010.