

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

Tamakawa S, Ogawa H. The effect of shakuyaku-kanzo-to and goshakusan on lumbago. *Itami to Kampo (Pain and Kampo Medicine)* 1997; 7: 83-5 (in Japanese with English abstract).

1. Objectives

To evaluate the clinical effect of shakuyakukanzoto (芍薬甘草湯) on acute lumbago (so-called strained back).

2. Design

Randomized controlled trial (RCT).

3. Setting

Asahikawa Medical College and Pain Clinic of Wakkanai City Hospital (two institutions), Japan.

4. Participants

Seventy patients who visited the above institutions and were diagnosed with acute lumbago within 1 week after onset (44 males and 26 females).

5. Intervention

Arm 1: epidural block with 0.125% bupivacaine, acupuncture, and poultices + TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 2.5 g t.i.d. before meals for 2 weeks (n=35).

Arm 2: epidural block with 0.125% bupivacaine, acupuncture, and poultices for 2 weeks (n=35).

6. Main outcome measures

Improvement in subjective symptoms of lumbago assessed on a 3-point scale: marked remission of lumbago (marked response), improvement in daily living but with persistent pain (moderate response), and limitations in daily living despite remission of lumbago (no response).

7. Main results

In the shakuyakukanzoto arm, 10 patients had marked response and 18 had moderate response, while in the control arm, 8 had marked response and 12 had moderate response; there was no significant between-arm difference. However, only 7 patients in the shakuyakukanzoto arm and 15 in the control arm had no response. In this study, 5 patients with chronic lumbago who complained of *jokan-genetsu* (上寒下熱, upper body heat and lower body cold) (in terms of Kampo medicine) received goshakusan, which resulted in a marked response in 3 patients and a moderate response in 2 patients.

8. Conclusions

Shakuyakukanzoto was administered for strained back to relieve myotonia without *sho* (証, pattern) diagnosis (証診断). Since shakuyakukanzoto seems to be effective, it can be used as a symptomatic treatment in clinical practice.

9. From Kampo medicine perspective

Shakuyakukanzoto, which has two flavors known as shiroshakuyaku (白芍薬) and kanzo (甘草), strongly relaxes smooth muscles.

10. Safety assessment in the article

No corticoid-like effects due to kanzo were experienced.

11. Abstractor's comments

This study took a Kampo medical approach to the treatment of strained back. Although epidural block with local anesthetics has been used for the treatment of strained back, its efficacy is inadequate in about half of patients whose symptoms are refractory. To improve efficacy, it can be combined with oral non-steroidal anti-inflammatory drugs (NSAIDs). However, NSAIDs have GI adverse effects that may inevitably result in the drug withdrawal. To resolve these problems, authors applied the strong muscle-relaxing effects of shakuyakukanzoto. Fewer patients seemed to have no response in the shakuyakukanzoto group. This result is encouraging to clinicians because it indicates that shakuyakukanzoto (without being a treatment based on *sho*) provides some symptomatic relief. Unfortunately, patients treated with only epidural block, acupuncture, and poultices in the control group also had a marked response, and there was no between-group difference in the response rate. Consequently, this was a controlled study in which the control treatment might also be highly effective. A study of simpler design (e.g., a controlled trial with poultices) to confirm the clinical efficacy of shakuyakukanzoto is expected. In this paper, favorable treatment outcomes with goshakusan (五積散) given according to *sho* for patients with chronic lumbago were also described, so further studies on practical treatment with Kampo medicine for lumbago are expected.

12. Abstractor and date

Ushiroyama T, 13 August 2008, 6 January 2010, 1 June 2010.