

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

Ohta H, Makita K. Lumbago - with emphasis on nonspecific lumbago, which obstetricians and gynecologists think is the most common form in women - . *Chiryō (The Journal of Therapy)* 1995; 77: 1646-57 (in Japanese). [MOL](#), [MOL-Lib](#)

1. Objectives

To clinically evaluate the effects of keishibukuryogan (桂枝茯苓丸) and its combination with bushi (附子) on nonspecific lumbago in women during menopause.

2. Design

Randomized controlled trial (RCT).

3. Setting

One facility (currently the first author is affiliated with Outpatient Department for Climacteric Disorders, Tokyo Women's Medical University Hospital), Japan.

4. Participants

Thirty-seven female patients with lumbago.

5. Intervention

Arm 1: keishibukuryogan (桂枝茯苓丸) (manufacturer unknown) 2.5 g t.i.d. before meals for 3 months (n=14).

Arm 2: keishibukuryogan (桂枝茯苓丸) (manufacturer unknown) 2.5 g t.i.d. + crude drug shujibushimatsu (manufacturer unknown) 0.17 g t.i.d. before meals for 3 months (n=23).

6. Main outcome measures

Lumbago symptoms (4-point scale) evaluated after 12 weeks of treatment: complete response (increase of 2 or more points) and partial response (increase of 1 point).

7. Main results

Complete response and partial response were respectively achieved in 21.4% and 14.3% of patients receiving keishibukuryogan alone and 26.1% and 34.8% of patients receiving keishibukuryogan + shujibushimatsu.

8. Conclusions

Combining keishibukuryogan with shujibushimatsu improves nonspecific lumbago in women during menopause, indicating that a *kuoketsu* (驅才血, blood stasis-expelling) Kampo medicine is clinically useful when combined with bushi, a crude drug with an analgesic/anti-inflammatory effect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Nonspecific lumbago in women during menopause has various etiologies and is not unambiguously related to the presence of inflammation and impaired blood flow. To treat it, therefore, various measures should be tried. This study produced favorable results using a therapy combining bushi (a pain reliever and blood flow enhancer) with keishibukuryogan, which is used to treat *oketsu* (才血, blood stasis), the most frequent pathology in women with climacteric unidentified complaints and a useful reference for many clinicians. It would be interesting to incorporate into the study protocol the theory of Kampo medicine, including choice of *kuoketsuzai* (驅才血劑, blood stasis-expelling formula) according to the diagnosis of *oketsu* (才血, blood stasis), and combination with bushimatsu taking the presentation of a feeling of coldness into consideration. A case series investigation incorporating the measurement of biomarkers is expected.

12. Abstractor and date

Ushiroyama T, 13 August 2008, 1 June 2010.