Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Nishizawa Y, Nishizawa Y, Yoshioka H, et al. Efficacy and safety of Chinese traditional medicine, niu-che-shwn-qi-wan (Japanese name: goshajinki-gan) versus propiverine hydrochloride on health-related quality of life in patients with overactive bladder in prospective randomized comparative study. *Kampo to Saishin-chiryo (Kampo & the Newest Therapy)* 2007; 16: 131-42 (in Japanese). Ichushi Web ID: 2007260946

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) and propiverine hydrochloride for overactive bladder.

2. Design

A randomized controlled trial (RCT).

3. Setting

Not mentioned (authors belong to Nishizawa Clinic, Department of Pathology and Applied Neurobiology, Kyoto Prefectural University of Medicine and Department of Anesthesiology, Shiga University of Medical Science), Japan.

4. Participants

Seven hundred and four patients with overactive bladder, aged 45 years or older, prospectively enrolled over a 10-year period (1997–2006).

5. Intervention

Arm 1: administration of goshajinkigan (牛車腎気丸) (manufacturer not specified), 4.5 g/day, for 1 year (n=352).

Arm 2: administration of propiverine hydrochloride, 60 mg/day, for 1 year (n=352).

6. Main outcome measures

Symptoms of overactive bladder (urge to urinate, daytime urinary frequency, nocturia, and urine leak). Quality of life (pain, erection dysfunction, cold sensation, etc.).

7. Main results

Symptoms of overactive bladder were significantly more improved in arm 2 than in arm 1 during the first month after treatment initiation, but significantly more improved in arm 1 than arm 2 during the second and subsequent months. At the completion of the study, the other concomitant symptoms and quality of life (QOL) were also significantly more improved in arm 1 than in arm 2.

8. Conclusions

It is suggested that goshajinkigan is effective for overactive bladder.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

Four and 375 events of adverse drug reactions occurred in arm 1 and arm 2, respectively.

11. Abstractor's comments

This 1-year prospective randomized controlled trial in 704 patients suggests the efficacy of goshajinkigan for overactive bladder. Its efficacy for concomitant symptoms and QOL was also suggested. However, there is no mention of the number patients who withdrew, the facility or facilities where this trial was actually conducted, and the method of randomization. Future studies considering these points are awaited.

12. Abstractor and date

Okabe T, 28 November 2008, 1 June 2010.