

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Ishizuka O, Yamanishi T, Gotoh M, et al. LUTS: new evidence – clinical efficacy of Kampo formulations focusing on goshajinkigan - . *Urology View* 2009; 7: 81-41. Ichushi Web ID: 2009114396

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) for relieving lower urinary tract symptoms (LUTS) in patients with benign prostatic hyperplasia (BPH) and concomitant overactive bladder (OAB).

2. Design

Randomized controlled trial (cross over) (RCT-cross over).

3. Setting

Multiple institutions (urology departments in 5 university hospitals including Shinshu University), Japan.

4. Participants

Eighteen male patients aged under 80 years with BPH, concomitant OAB, and urinary frequency and urgency even after receiving 8-week treatment with tamsulosin hydrochloride.

5. Intervention

Arm 1: tamsulosin hydrochloride 0.2 mg/day + TSUMURA goshajinkigan (牛車腎気丸) Extract Granules 7.5 g/day for 4 weeks, followed by monotherapy with tamsulosin hydrochloride 0.2 mg/day for 4 weeks (n=9).

Arm 2: tamsulosin hydrochloride 0.2 mg/day for 4 weeks, followed by tamsulosin hydrochloride 0.2 mg/day + TSUMURA goshajinkigan (牛車腎気丸) Extract Granules 7.5 g/day for 4 weeks (n=9).

6. Main outcome measures

OAB symptoms (frequencies of daytime urination, nighttime urination, urgency, and incontinence), BPH symptoms (International Prostate Symptom Score [IPSS], postvoid residual urine volume), King's Health Questionnaire (KHQ), and quality of life (QOL) index.

7. Main results

Comparing the combination therapy period and the monotherapy period, there were no significant differences in frequencies of daytime urination, nighttime urination, and urgency ($P=0.225$, $P=0.882$, and $P=0.348$, respectively). The QOL index improved significantly ($P=0.008$) and the frequency of incontinence tended to improve, though not significantly, during the combination therapy period ($P=0.090$). No significant differences were found in IPSS ($P=0.563$), postvoid residual urine volume ($P=0.846$), and KHQ score.

8. Conclusions

The concomitant use of goshajinkigan improves QOL but not urinary urgency in patients who have OAB symptoms after treatment with tamsulosin hydrochloride for BPH.

9. From Kampo medicine perspective

It was mentioned in the “discussion” section.

10. Safety assessment in the article

Gastric distress and diarrhea occurred in one goshajinkigan-treated patient each.

11. Abstractor's comments

This study reports that the concomitant use of goshajinkigan did not improve frequency of urination or urinary urgency, but did improve QOL in patients with BPH who had OAB symptoms after the treatment with tamsulosin hydrochloride, an α 1-receptor blocker. In the practice of Kampo medicine, goshajinkigan is effective for nocturia. Demonstration of the efficacy of this agent requires selection of patients based on differential diagnosis using Kampo medicine-based criteria (*sho* [証, pattern]), such as *kan-netsu* (寒熱, cold and heat) and *kyo-jitsu* (虚実, excess or deficiency), as the authors mentioned in the discussion. Clinical trials with a new design are needed.

12. Abstractor and date

Okabe T, 1 June 2010, 31 December 2013.