

**18. Symptoms and Signs****References**

**Shimizu Y, Yoshimura K, Soda T, et al. The effects of gosha-jinki-gan, a blended herbal medicine, and furosemide for nocturnal polyuria with elevated B-type natriuretic peptide: a crossover trial. *Neurourology and Urodynamics* 2010; 29: 833–4. CENTRAL ID: CN-00766683**

Yoshimura K, Shimizu Y, Masui K, et al. Furosemide versus gosha-jinki-gan, a blended herbal medicine, for nocturnal polyuria: a randomized crossover trial. *Lower Urinary Tract Symptoms* 2012; 4: 77-81.

**1. Objectives**

To evaluate the effectiveness of goshajinkigan (牛車腎気丸) for nocturnal polyuria with elevated B-type natriuretic peptide (BNP).

**2. Design**

Crossover randomized controlled trial (RCT – cross over).

**3. Setting**

No information about location of the trial (the first author belongs to the Department of Urology, Kyoto University), Japan.

**4. Participants**

Twenty-four patients over 50 years with a nocturia frequency of more than three times/night, a nocturnal polyuria index of more than 35%, and serum BNP level of over 20 pg/mL.

**5. Intervention**

Arm 1: goshajinkigan (牛車腎気丸) (manufacturer not identified) 2.5 g t.i.d. for 4 weeks, then furosemide 20 mg q.d. (p.m.) for 4 weeks (n=14).

Arm 2: furosemide 20 mg once/day (p.m.) for 4 weeks, then goshajinkigan (牛車腎気丸) (manufacturer not identified) 2.5 g t.i.d. for 4 weeks (n=10).

**6. Main outcome measures**

International Prostate Symptom Score (IPSS), Pittsburgh Sleep Quality Index (PSQI), frequency volume chart (FVC), blood pressure, serum BNP, and total body water assessed before and after each administration.

**7. Main results**

Mean age of participants was 73.8 years (54–85 years). Nocturia frequency and volume decreased significantly with furosemide administration compared to goshajinkigan administration (both  $P<0.05$ ). However, IPSS-7, IPSS-QOL, and nocturia frequency improved significantly with both goshajinkigan and furosemide in before/after comparisons ( $P<0.05$ ,  $P<0.01$ ,  $P<0.05$  for the three measures respectively with goshajinkigan, and  $P<0.01$  for all three measures with furosemide). IPSS-total and nocturia volume improved significantly only with furosemide (both  $P<0.01$ ). Nocturia volume decreased markedly with furosemide administration but only slightly with goshajinkigan administration. PSQI scores and subjective sleep scores improved significantly only with furosemide (both  $P<0.05$ ).

**8. Conclusions**

Furosemide is more effective for nocturnal polyuria associated with elevated BNP, but goshajinkigan may be almost as effective.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This clinical study investigated the effectiveness of goshajinkigan for nocturnal polyuria associated with elevated B-type natriuretic peptide. By classifying the causes of subjects' condition (nocturnal polyuria), effective condition for using goshajinkigan can be identified. The paper subsequently published by Yoshimura et al (2012) includes 36 participants and reports similar results, but it describes in detail the research methods they employed. Goshajinkigan may be effective for patients with slight nocturnal polyuria symptoms or patients who cannot take furosemide due to its adverse effects, which include electrolyte disturbance. It is, therefore, a highly significant clinical study.

**12. Abstractor and date**

Goto H, 31 December 2012, 31 December 2013.