

CLINICAL EFFICACY AND TOLERABILITY OF GOSHA-JINKI-GAN, CHINESE TRADITIONAL HERBAL MEDICINE, IN FEMALES WITH OVERACTIVE BLADDER

Hypothesis / aims of study

To evaluate the efficacy and tolerability of a single-agent treatment with Gosha-jinki-gan, Chinese traditional herbal medicine, in females diagnosed as having overactive bladder (OAB) through an objective analysis with three linguistically validated questionnaires.

Study design, materials and methods

Among patients who consulted the outpatient clinic with a chief complaint of OAB symptoms between October 2004 and May 2005, a total of 52 females diagnosed as having OAB were considered for enrollment. Patients with proven infections, neurogenic bladder disease or other obvious pathology were excluded. They received a single-agent treatment with 7.5 g/day Gosha-jinki-gan orally for 8 weeks. Before and after the treatment, the International Prostate Symptom Score (IPSS) and QOL index were examined, and the number of voids during the daytime and sleep was also counted for 2 days. Post voided residual urine (PVR) was evaluated by ultrasonography. In addition, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was also distributed to patients with urge incontinence (wet OAB) before and after the study. The efficacy assessment was done by comparing the QOL scores after 8 weeks of administration to those at the baseline. Tolerability of the treatment was assessed by medical interview at every visit to the outpatient clinic to determine adverse events. Adverse reactions to Gosha-jinki-gan were also elucidated carefully. Statistical analyses were undertaken using the non-parametric Mann-Whitney U-test and Wilcoxon signed rank test, with $p < 0.05$ considered to indicate statistical significance.

Results

1. Efficacy and tolerability of Gosha-jinki-gan; As 8 patients dropped out during the study (2 patients because of cure or improvement, 3 who switched to anticholinergics, one who was diagnosed as having interstitial cystitis during 8 week treatment, and 2 who did not revisit), a total of 44 patients (aged 51 to 83 years, mean 66.8 ± 15.3 years) treated with Gosha-jinki-gan for 8 weeks were evaluated. Prevalence rates of OAB with and without urge incontinence were 63.6% and 36.4%, respectively. Objective evaluation with the QOL questionnaire yielded a result of excellent in 3 patients (6.8%), improved in 20 (45.5%), unchanged in 18 (40.9%), and deteriorated in 3 (6.8%). Our results demonstrated that Gosha-jinki-gan was effective in 23 (52.3%) of the 44 patients. Adverse reactions to the treatment were observed in 4 (9.1%) of the patients; gastric discomfort in 2 patients, nausea in one and loose bowels in one. No patients discontinued the treatment due to these adverse events.

2. Urinary symptoms; After 8-week treatment, the IPSS total scores and QOL scores were significantly reduced. The number of voids during the daytime and during sleep was also significantly decreased (Table 1). PVR was not increased in any of the patients after treatment.

3. Comparison between wet OAB and dry OAB; Comparison of patients showing dry OAB (63.6%; $n=28$) with those showing wet OAB (36.4%; $n=16$) revealed excellent and improved QOL in 67.9% and 25.0% respectively, the difference between the two groups being significant ($p < 0.01$) (Table 2). Comparison of the dry OAB and wet-OAB showed significant difference in age between the two subtypes (61.2 ± 16.4 v.s. 76.7 ± 5.2 ; $p = 0.0002$). The decrease in ICIQ-SF total scores in the wet OAB group was, of course, not significant (11.6 ± 2.7 pretreatment v.s. 9.8 ± 3.1 at 8 weeks of administration).

Interpretation of results

The major drawbacks of this study are that there was no control-group nor randomization. However, Gosha-jinki-gan statistically reduced daytime frequency of voids and nocturia, and the IPSS total scores, resulting in the improvement of QOL in females with OAB. This drug was more effective in females with dry OAB than with wet OAB.

Concluding message

Our results demonstrate the evidence that Gosha-jinki-gan could be a safe and effective potential therapeutic alternative in females with OAB, especially with dry OAB.

Table 1 Plus-minus values are means \pm SD.

Age (yrs) n=44	IPSS (point)		QOL scores (point)		Urinary frequency (during the daytime)		Urinary frequency (during sleep)	
	pre	post	pre	post	pre	post	pre	post
66.8 ± 15.3	14.2 ± 4.9	10.0 ± 6.0	4.2 ± 0.7	3.1 ± 1.3	9.3 ± 1.8	7.8 ± 1.7	2.7 ± 1.7	2.2 ± 1.7
p value	$p < 0.0001$		$p < 0.0001$		$p < 0.0001$		$p = 0.0001$	

Table 2 % (n), Plus-minus values are means \pm SD. * $p = 0.0002$, ** $p < 0.01$

	*Age (yrs)	Excellent	Improved	Unchanged	Worsened	**Success rate
Dry OAB n=28	61.2 ± 16.4	10.7% (3)	57.1% (16)	25.0% (7)	7.1% (2)	67.9% (19)
Wet OAB n=16	76.7 ± 5.2	0% (0)	6.3% (4)	68.8% (11)	6.3% (1)	25.0% (4)

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DISCLOSURES: NONE

HUMAN SUBJECTS: This study did not need ethical approval because no appropriate ethics committee in our hospital but followed the Declaration of Helsinki Informed consent was obtained from the patients.