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THE EFFECTS OF GOSHA-JINKI-GAN, A BLENDED HERBAL MEDICINE, AND FUROSEMIDE FOR NOCTURNAL POLYURIA WITH ELEVATED B-TYPE NATRIURETIC PEPTIDE: A CROSSOVER TRIAL.

Hypothesis / aims of study

Nocturnal polyuria (NP) is one of the main causes of nocturia, which has a negative impact on quality of life. Lifestyle modification may provide benefit in some individual, but for many, the only option is pharmacotherarapy which is desmopressin or time release diuretics (1). However, desmopressin and diuretics have a potential risk of adverse effect such as serum electrolyte abnormalities. Gosha-Jinki-Gan (GJG), traditional Japanese herbal medicine, has been used for the overactive bladder (2) and reported to be effective for nocturia with elevated B-type natriuretic peptide (BNP) suspect of due to mild diuretic effect (3). The effectiveness of GJG for NP has not been established. The aim of this study was to test the efficacy of GJG for NP with elevated BNP, compared with furosemide .

Study design, materials and methods

Patients with NP were enrolled in a crossover trial. The Inclusion criteria were age≥50 years, nocturia≥3 voids/night, nocturnal polyuria index (NPi) ≥35% and serum BNP≥20pg/ml. Patients were stratified into two groups; patients in group A were initially prescribed GJG 7.5g three times a day for 4 weeks, followed by furosemide 20mg once a day in the afternoon for 4 weeks, and those in group B were initially prescribed furosemide 20mg, followed by GJG 7.5g. The International Prostate Symptom Score (I-PSS), the Pittsburgh Sleep Quality Index (PSQI), frequency volume chart (FVC), blood pressure, serum BNP and the total amount of body water were used to assess the efficacy of the therapy. Wilcoxon signed-rank test were used for statistical analysis. $P<0.05$ was considered statistically significant.

Results

Twenty-four patients (19 men and 5 women) were randomly divided into two groups. 14 patients were classified in group A and 10 patients in group B. The mean age was 73.8 years (range 54-85). The results of I-PSS and FVC are showed in the table1. Nocturnal frequency and nocturnal urine volume were reduced more significantly by furosemide treatment than GJG treatment. However, compared with baseline, both GJG and furosemide produced significant improvements in I-PSS-7, I-PSS-QOL and nocturnal frequency. I-PSS-total score and nocturnal urine volume improved significantly only by furosemide treatment.
Marked decrease in nocturnal urine excretion was observed after furosemide, while mild decrease was observed also after GJG (Figure 1). Improvement of global PSQI score and subjective sleep quality score was observed only by furosemide treatment (p=0.02 and p=0.02, respectively). In the total amount of body water and BNP, no differences were observed after both treatments. Systolic blood pressures became significantly lower only after furosemide treatment.

Interpretation of results

Furosemide reduced nocturnal voided volume due to diuretic effect during daytime and remarkably improved nocturnal frequency and QOL. In the case of GJG, mild improvement of nocturnal frequency and I-PSS-QOL were observed.

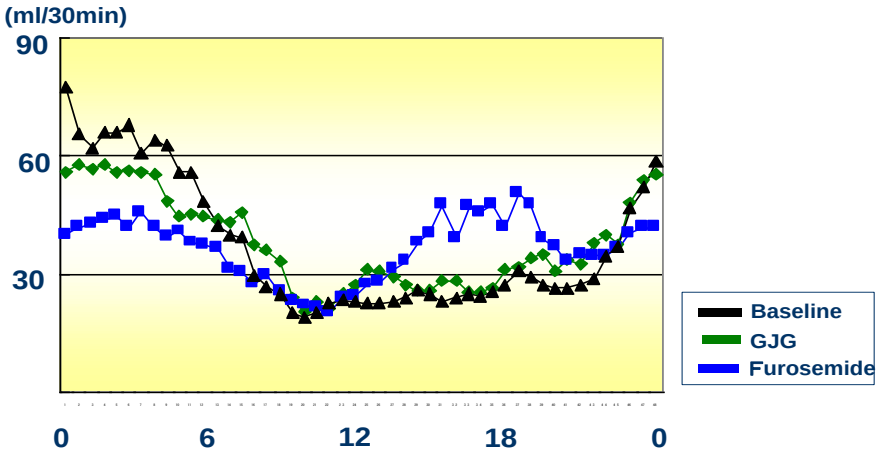
Concluding message

Both furosemide and GJG were effective in the treatment of NP with elevated BNP. Furosemide was more effective because of its strong diuretic effect. However, GJG could be one of options for treatment of NP as well.

Table 1: Results of IPSS and FVC

	baseline (B)	GJG (G)	furosemide (F)	P (B vs G)	P (B vs F)	P (G vs F)
IPSS-total	12.1	10.4	9.6	NS	<0.01	NS
IPSS-7	3.7	3.2	3	0.03	<0.01	NS
IPSS-QOL	5	3.9	4.2	<0.01	<0.01	NS
24fr frequency	10.2	10.4	10.4	NS	NS	NS
daytime frequency	5.9	6.5	7.1	NS	0.005	NS
nocturnal frequency	4.3	4	3.2	0.036	<0.001	0.026
24hr-vol (ml)	1802	1821	1755	NS	NS	NS
day vol (ml)	828	937	1034	NS	0.003	NS
nocturnal Vol (ml)	974	884	721	NS	0.002	0.017

Figure 1. 24h rhythm of urine excretion



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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Kyoto University Ethical Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**