

18. Symptoms and Signs

Reference

Ishioka T. Comparison of the efficacy of goreisan and saireito for mild edema of the dorsum of the foot in elderly subjects stratified by physical strength*. *Kampo no Rinsho (Journal of Kampo Medicine)* 1997; 44: 1091-5 (in Japanese).

1. Objectives

To compare the efficacy of goreisan (五苓散) and saireito (柴苓湯) for mild edema of the dorsum of the foot in the elderly.

2. Design

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

3. Setting

A special nursing home, Japan.

4. Participants

Forty-three patients who were admitted to the nursing home, had no serious cardiac diseases, had a serum creatinine level within normal limits, and complained of mild persistent edema of the dorsum of the foot (9 males and 34 females, aged 66-94 years, mean age 83.1 years). Of these 43 patients, 21 were placed into a "moderate physical strength" subgroup and 22 into a "low physical strength" subgroup, on the basis of strength demonstrated during a balloon volleyball game played in the nursing home.

5. Intervention

Arm 1: treatment with TSUMURA Goreisan (五苓散) Extract Granules 2.5 g t.i.d. for 2 weeks, then switched, with no wash-out, to TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. for 2 weeks. The sample size was not reported.

Arm 2: treatment with TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. for 2 weeks, then switched, with no wash-out, to TSUMURA Goreisan (五苓散) Extract Granules 2.5 g t.i.d. for 2 weeks. The sample size was not reported.

6. Main outcome measures

Disappearance of edema after 2 weeks of treatment was rated as "moderate response"; marked reduction of edema as "mild response"; no change as "no response"; and symptomatic exacerbation requiring diuretics after 1 week, or marked exacerbation after 2 weeks of treatment as "worsening". The two drugs were considered as "having comparable efficacy" when the extent of symptomatic changes during the first and the second 2 weeks were similar.

7. Main results

One patient was hospitalized with bronchitis on day 3 of the saireito treatment following the goreisan treatment. Consequently, the efficacy of goreisan but not saireito was evaluated in this patient. As a result, efficacy analysis population included 43 patients for goreisan and 42 for saireito. A "mild" or better response was obtained in 67% of the goreisan-treated and 62% of the saireito-treated patients; the difference was not significant. In the subgroup with moderate physical strength, there was no significant difference in the rate of response to goreisan (57%) and saireito (62%). In contrast, the rate of response to goreisan (77%) tended to higher than that to saireito (62%; $P < 0.1$) in the subgroup with low physical strength.

8. Conclusions

Both goreisan and saireito results in a "mild" or better response in 60% or more of the elderly patients with mild edema of the dorsum of the foot. Notably, patients with low physical strength tended to be more responsive to goreisan.

9. From Kampo medicine perspective

The author argued that the classification "low physical strength" is almost identical to the definition of weak constitution in the clinical guidelines for the reevaluation of Kampo extract preparations, and that "low physical strength" and weak constitution are consistent with the Kampo concept of *kyo-sho* (虚証, deficiency pattern).

10. Safety assessment in the article

Although no individual patients developed abnormalities while taking the test drugs, a decrease in potassium level in all patients and an elevated serum creatinine level in the subgroup with low physical strength were observed. Subjective or objective symptoms were not reported.

11. Abstractor's comments

This study was a cross-over trial conducted in a special nursing home. There are some problems with the study design, such as the absence of wash-out period and the non-blinded design. The development of further studies is expected.

12. Abstractor and date

Tsuruoka K, 25 April 2008, 1 June 2010, 31 December 2013.