12. Skin diseases

Reference

Nagai Y, Hasegawa M, Tago O, et al. Assessment of the therapeutic effect of juzentaihoto on pressure ulcer. *Kampo to Saishin-chiryo* (*Kampo & The Newest Therapy*) 2009;18:143-9. Ichushi Web ID: 2009244595

1. Objectives

To evaluate the effects of juzentaihoto (十全大補湯) on pressure ulcers.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Department of Dermatology, Gunma University Hospital and eight affiliated hospitals, Japan.

4. Participants

Twenty-eight chronic-phase patients whose pressure ulcers showed no change or worsening during a 2-week observation period (age and sex, not specified).

5. Intervention

Arm 1: TSUMURA Juzentaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. orally before or after meals for 12 weeks. For patients with a body weight below 35 kg, the drug was administered b.i.d (n=16, including 12 infected with methicillin-resistant *Staphylococcus aureus* [MRSA]).

Arm 2: continuation of conventional treatment (n=12, including 5 infected with MRSA).

6. Main outcome measures

Long × short axes, size, and depth of pressure ulcers; prealbumin level, serum albumin level, lymphocyte count, prognostic nutritional index, serum hemoglobin level, and bacterial culture from the site of pressure ulcer (scoring from – to 3+) were measured at baseline, 4, 8, and 12 weeks.

7. Main results

There were no between-arm differences in the size of pressure ulcers, prealbumin level, and prognostic nutritional index. Detection of methicillin-resistant *Staphylococcus aureus* (MRSA) declined significantly during the course of treatment in arm 1 compared with arm 2 ($P<0.05$).

8. Conclusions

Oral administration of juzentaihoto lowers the detection rate of MRSA but has no effect on the healing rate of pressure ulcers or nutritional status.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This is an interesting clinical study that evaluated the effects of juzentaihoto on various aspects of outcome, including improvement rate, nutritional status, and local antibacterial activity, in chronic-phase patients. The data of 28 patients were analyzable in this study, but the number of patients initially enrolled, including withdrawals, is not reported. Moreover, data on age, sex, underlying disease, and presence of complications are not available. Although prealbumin level, prognostic nutritional index, serum albumin level, lymphocyte count, and serum hemoglobin level were measured, only prealbumin level and prognostic nutritional index are reported. Thus, a more detailed report is desired. As for prealbumin level and prognostic nutritional index, the authors reported "no differences" in the results section based on the lack of significant between-arm differences, whereas they reported "better in arm 1" in the summary section based on the higher mean values in arm 1; the lack of significant differences should have been mentioned. Yet, as the authors noted, the disease course may be better (albeit not significantly) in patients who take juzentaihoto than in those who do not. Future studies including a larger number of patients and a longer follow-up might demonstrate the efficacy of juzentaihoto in patients with chronic pressure ulcers.

12. Abstractor and date

Goto H, 1 June 2010.