

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Watanabe H. A study of peptic ulcer maintenance therapy combined with Kampo medicines*. *Kampo Igaku (Kampo Medicine)* 1995; 19: 18-21 (in Japanese).

1. Objectives

To evaluate the usefulness of H₂-blocker (cimetidine) combined with Kampo medicine (shigyakusan [四逆散], saikokeishito [柴胡桂枝湯]) as a maintenance therapy for peptic ulcer.

2. Design

Randomized controlled trial (RCT).

3. Setting

Single institution (Department of Gastroenterology, Matsudo City Hospital), Japan.

4. Participants

Thirteen patients who were confirmed to have peptic ulcer (8 with gastric ulcer, 5 with duodenal ulcer) by upper gastrointestinal endoscopy, and received two-month initial therapy (H₂-blocker + protective factor-enhancing agent combination) and one-year maintenance therapy.

5. Intervention

Arm 1: treatment with cimetidine 400 mg s.i.d. (before bedtime) + Kampo medicine twice daily (morning and evening) (n=7; TSUMURA Shigyakusan Extract Granules (四逆散) 2.5 g b.i.d. [n=4], TSUMURA Saikokeishito Extract Granules (柴胡桂枝湯) 2.5 g b.i.d. [n=3]).

Arm 2: treatment with cimetidine 400 mg s.i.d. (before bedtime) + sucralfate 1.0 g b.i.d. (morning and evening) (n=6).

6. Main outcome measures

Recurrence of ulcer, change in ulcer scar stage, and improvement of redness of the gastric antral mucosa.

7. Main results

The effects were evaluated by upper gastrointestinal endoscopy after a year of treatment. No recurrence was observed in either arm. In 4 of 6 patients (66.7%) in the sucralfate group and 5 of 7 (71.4%) in the Kampo group, scars had improved from stage S₁ at the start of maintenance therapy to stage S₂ at 1 year. In cases with marked redness of gastric antral mucosa, mild improvement was observed in 2 (33%), no change in 3 (50%), and worsening in 1 (17%) of 6 sucralfate-treated patients; moderate improvement was observed in 1 (25%) and mild improvement in 3 (75%) of 4 shigyakusan-treated patients.

8. Conclusions

Kampo medicine (TSUMURA Shigyakusan Extract Granules, TSUMURA Saikokeishito Extract Granules) plus H₂-blocker (cimetidine) combination therapy is likely to have remarkable efficacy for preventing recurrence of ulcer.

9. From Kampo medicine perspective

Based on the endoscopic findings, patients with marked redness and irregularity of gastric antral mucosa, which is regarded as *jitsu-sho* (実証, excess pattern), were assigned to the shigyakusan treatment, and patients with less evident findings, which is regarded as *kyo-sho* (虚証, deficiency pattern), to the saikokeishito treatment.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

With the recent advent of *Helicobacter pylori* eradication therapy for peptic ulcer, recurrence of ulcer and incidence of gastric cancer have remarkably decreased. However, some patients are reported to fail or be ineligible for the eradication therapy. This study may be, even now, very meaningful for those cases. Some points need further clarification, including incomplete statistical evaluation of the efficacy owing to the small sample size, the possibility that the patient population was atypical in that no one developed recurrence of ulcer, and the need for a description of adverse drug reactions. In addition, patients were assigned to the shigyakusan or saikokeishito treatment based on the author's empirical rule; this point also needs reconsideration. The study will be more meaningful when these points are considered and a larger number of patients are enrolled.

12. Abstractor and date

Arai M, 18 October 2008, 1 June 2010, 31 December 2013.