

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

Nakahara A, Kashimura H, Fukutomi H. Gastric ulcer - saikokeishito or shigyakusan monotherapy - . *Nikkei Medical* (separate-volume supplement) 1988; 17: 20-1 (in Japanese).

Fukutomi H, Nakahara A. Traditional oriental therapy of the gastric ulcer. *Shokakika (Gastroenterology)* 1990; 12: 159-65 (in Japanese)

1. Objectives

To compare the efficacy of saikokeishito (柴胡桂枝湯), H₂ receptor antagonist, or their combination for preventing recurrence of gastric ulcer.

2. Design

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

3. Setting

Fifty-one institutions (names are not specified; the authors belong to the Institute of Clinical Medicine, University of Tsukuba), Japan.

4. Participants

One hundred and eighty-nine patients whose gastric ulcer was healed by treatment with the combination of TSUMURA Saikokeishito Extract Granules and H₂ receptor antagonist.

5. Intervention

Arm 1: treatment with TSUMURA Saikokeishito Extract Granules (柴胡桂枝湯) 5.0 g/day (TJ-10 group; n=40).

Arm 2: treatment with H₂ receptor antagonist 400 mg/day (H₂-blocker group; n=32).

Arm 3: treatment with TSUMURA Saikokeishito Extract Granules plus H₂ receptor antagonist (combined group; n=54)

The dose was halved after month 4.

6. Main outcome measures

Recurrence of gastric ulcer.

7. Main results

The cumulative recurrence rate (calculated monthly) was around 24% at 6 months and similar for all three groups. In patients aged under 50 years, the recurrence rate was lowest after treatment with the combination, whereas in patients aged 50 years or older, the rate was around 20% and not different among the three groups.

8. Conclusions

For patients aged 50 or older, saikokeishito monotherapy is the preferred maintenance therapy for gastric ulcer because (unlike receptor antagonist) it is less associated with age-related reduction of drug metabolizing capacity and adverse reactions.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinically valuable report showed that the effectiveness of saikokeishito is comparable to that of H₂ receptor antagonist as a maintenance therapy for gastric ulcer. Because the cumulative rates of recurrence for the three groups were similar and the Kampo medication caused fewer adverse reactions, the authors concluded that Kampo therapy is a treatment of choice for patients aged 50 or older. However, the paper contains no results or discussion regarding adverse drug reactions. So the submission as an original article is desired, and descriptions of adverse drug reactions should be included.

12. Abstractor and date

Arai M, 18 October 2008, 6 January 2010, 1 June 2010, 31 December 2013.