

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

Ishii F, Iizuka B, Nagasako K, et al. Evaluations of the therapeutic efficacy of Saikokeishito (TJ-10) versus Keishikashakuyakuto (TJ-60) for irritable bowel syndrome and Saireito (TJ-114) for ulcerative colitis. *Progress in Medicine* 1993; 13: 2893-900 (in Japanese).

1. Objectives

To compare the efficacy of saikokeishito (柴胡桂枝湯) and keishikashakuyakuto (桂枝加芍藥湯) for irritable bowel syndrome (IBS).

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned (authors belong to the Department of Internal Medicine, Institute of Gastroenterology, Tokyo Women's Medical University), Japan.

4. Participants

Forty-six patients clinically diagnosed with IBS. Patients were excluded for the following reasons: (i) medications (e.g., anticholinergics, tranquilizers), given within the previous week, possibly influencing the evaluation; (ii) complications including organic diseases of the gastrointestinal tract and bacterial infections.

5. Intervention

Arm 1: treatment with TSUMURA Saikokeishito Extract Granules (柴胡桂枝湯) 2.5 g t.i.d. (n=23) for 2 weeks.

Arm 2: treatment with TSUMURA Keishikashakuyakuto Extract Granules (桂枝加芍藥湯) 2.5 g t.i.d. (n=23) for 2 weeks.

6. Main outcome measures

Epigastric pain, lower abdominal pain, anorexia, abdominal bloating, feeling of retension, diarrhea, constipation, alternating diarrhea and constipation, flatulence /borborygmus, and feeling of incomplete evacuation.

7. Main results

The response was evaluated on a 4-point scale (marked, moderate, mild, none) and by comparing outcome measures before and after two weeks of treatment. Marked or moderate response was observed in 9 of 23 patients (39%) in arm 1 and 17 of 23 (74%) in arm 2. Regarding the pattern of bowel movements (diarrhea, constipation, and alternating diarrhea and constipation), the rate of marked or moderate response was 50% or more for all patterns in arm 2; in particular, it was 86% in those with alternating diarrhea and constipation. In arm 2, marked or moderate response was observed in 60% of patients with saikokeishito-type symptoms (epigastric pain, lower abdominal pain, and anorexia) and in 75% of those with keishikashakuyakuto-type symptoms (diarrhea, constipation, alternating diarrhea and constipation, abdominal bloating, stasis, flatulence/borborygmus, and feeling of incomplete evacuation). In arm 1, rates of marked or moderate response were under 50% in both symptom-based groups. Regarding individual symptoms, response rates were 50% for epigastric pain and 20–30% for the other symptoms in arm 1, whereas rates were 50% or more for alternating diarrhea and constipation, lower abdominal pain, diarrhea, constipation, and abdominal bloating in arm 2.

8. Conclusions

Keishikashakuyakuto can be prescribed to provide satisfactory effects for diagnostically confirmed IBS, irrespective of *sho* (証, pattern) or types of disease. Keishikashakuyakuto seems to act similarly to the anticholinergics or anxiolytics used in the medical therapy of IBS, and is recommended especially for patients with alternating-pattern of bowel movements.

9. From Kampo medicine perspective

The original study design included random assignment to the saikokeishito or keishikashakuyakuto treatment arms. During the analysis of results, response was evaluated separately in patients with saikokeishito-type clinical symptoms and those with keishikashakuyakuto-type symptoms.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This paper describes two different clinical studies. The latter part, in which therapeutic efficacy of saireito for ulcerative colitis was evaluated, was excluded from this Structured Abstract because it was not a randomized controlled trial. Many papers have been published on the efficacy of keishikashakuyakuto for IBS. The authors of this paper deserve praise for comparing keishikashakuyakuto with saikokeishito, which needs clinical differentiation. Since IBS can be a psychosomatic disease, it may be better to evaluate not only gastrointestinal symptoms, but also psychological items and systemic symptoms as measures of response. Furthermore, since IBS can be refractory, it might be better to consider treatment history and more. Further investigation of this clinically useful theme is expected.

12. Abstractor and date

Arai M, 21 October 2008, 6 January 2010, 1 June 2010.