

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

Koide A. Adoption of rikkunshito before endoscopy in patients with upper abdominal symptoms\*. *Nikkei Medical* 2002; 31: 22-3 (in Japanese).

Koide A. The improvement of QOL by rikkunshito in patients with need for endoscopy\*. *Medical Tribune* 2004: 45 (in Japanese).

**Yamaguchi T, Koide A. Usefulness of Rikkun-shi-to (TJ-43), a Chinese herbal medicine, for the treatment of gastro-esophageal reflux disease (GERD). *Medical Science Digest* 2007; 33: 748-52 (in Japanese).**

**1. Objectives**

To evaluate the efficacy of rikkunshito (六君子湯) as an agent to improve symptoms before endoscopy in patients with upper abdominal symptoms and need for endoscopy of the upper gastrointestinal tract.

**2. Design**

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

**3. Setting**

None; the authors are members of the Department of Medical Oncology, Graduate School of Medicine, Chiba University, Japan.

**4. Participants**

One hundred and twenty patients with upper abdominal symptoms and need for upper gastrointestinal endoscopy.

**5. Intervention**

Arm 1: treatment with H<sub>2</sub>-receptor blocker (H2RB; ranitidine 150 mg; n=39).

Arm 2: treatment with proton pump inhibitor (PPI; omeprazole 20 mg; n=40).

Arm 3: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g (n=41).

The duration of treatment was not specified (the administration was continued until the upper gastrointestinal endoscopy was performed).

**6. Main outcome measures**

Acid reflux (heartburn, reflux), abdominal pains (epigastric pain, hunger, and nausea), dyspepsia (borborygmus, abdominal distention, eructation, and flatus), diarrhea (diarrhea, loose stool, and rectal urgency), and constipation (constipation, hard stool, feeling of incomplete evacuation).

**7. Main results**

Overall, gastrointestinal symptoms associated with impaired quality of life (QOL) were significantly improved after the treatment in all arms; the improvement was significantly greater in arm 3 than in arms 1 and 2. Also improved were acid reflux associated with impaired QOL in arm 1, acid reflux and abdominal pains associated with impaired QOL in arm 2, and acid reflux, abdominal pains, and dyspepsia associated with impaired QOL in arm 3. Significantly greater improvements were found for acid reflux in arm 3 than in arm 1; for abdominal pains in arms 2 and 3 than in arm 1; for dyspepsia in arm 3 than in arms 1 and 2. Considering only patients with reflux esophagitis, gastrointestinal symptoms were also significantly improved by treatment in all arms. Acid reflux improved in arm 1, and acid reflux, abdominal pains, and dyspepsia improved in arms 2 and 3. H2RB, PPI, and rikkunshito had similar effectiveness.

**8. Conclusions**

The efficacy of rikkunshito as a pre-endoscopic medication, even as monotherapy, is comparable to that of other gastric acid secretion inhibitors in patients with upper abdominal symptoms and need for upper gastrointestinal endoscopy.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

The study by Yamaguchi et al (2007) is considered to be a follow-up to the two studies by Koide (2002, 2004). This clinically valuable study showed that the efficacy of rikkunshito against upper abdominal symptoms including gastroesophageal reflux disease is comparable to that of other gastric acid secretion inhibitors. The present study also deserves praise for assessing each clinical symptom objectively using the GSRS (Gastrointestinal Symptom Rating Scale). The cost-effectiveness of rikkunshito is mentioned without detail in the conclusion of this paper, but it is addressed more completely in paper 2). The present paper provides very interesting insights, but its first half is too general. Therefore, publication as an original article is desired.

**12. Abstractor and date**

Arai M, 15 June 2007, 1 April 2008, 20 January 2009, 1 June 2010, 31 December 2013.