

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

Suzuki H, Matsuzaki J, Fukushima Y, et al. Randomized clinical trial: rikkunshito in the treatment of functional dyspepsia - a multicenter, double-blind, randomized, placebo-controlled study. *Neurogastroenterology and Motility* 2014; 26: 950-61. CENTRAL ID: CN-00995379, Pubmed ID: 24766295

1. Objectives

To evaluate the treatment effects of rikkunshito (六君子湯) on functional dyspepsia.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

Multi-center study in 20 general hospitals and 11 clinics, Japan.

4. Participants

Two hundred forty-seven patients aged 20 years or older who had diagnosis of functional dyspepsia.

5. Intervention

Arm 1: Rikkunshito (六君子湯) extract granules (manufacturer unknown) 2.5 g t.i.d. before meals for 8 weeks (n=125).

Arm 2: Placebo before meals for 8 weeks (n=122).

6. Main outcome measures

Weekly change in the global patient assessment (GPA) score and Likert scale after rikkunshito administration; change in the Gastrointestinal Symptom Rating Scale (GSRS) score, anti-*Helicobacter pylori* IgG antibody level, and blood ghrelin concentrations from baseline to post-administration.

7. Main results

The proportion of participants showing symptom improvement as reflected in the GPA score was higher in the rikkunshito arm than in the placebo arm, but not significantly (33.6% vs. 23.8%; $P=0.09$). However, stomach pain was significantly more improved in the rikkunshito arm than in the placebo arm ($P=0.04$); postprandial abdominal distension also tended to improve ($P=0.06$), with greater improvement in the *H. pylori*-positive patients (40.0%) than in *H. pylori*-negative patients (20.0%) ($P=0.07$). The change in blood ghrelin concentration from baseline to post-administration was similar between the two arms.

8. Conclusions

Eight-week administration of rikkunshito improved dyspepsia symptoms especially stomach pain and postprandial distension. This indicated that rikkunshito has strong treatment effects on functional dyspepsia.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No clinically significant adverse drug reactions were reported. However, mild adverse drug reactions including diarrhea and nausea were found in 15.2% of subjects in the rikkunshito arm and 11.5% of subjects in the placebo arm (no significant difference).

11. Abstractor's comments

The main value of this study was its clinical evaluation of the treatment effects of rikkunshito for functional dyspepsia, which is widely used for upper gastrointestinal tract symptoms corresponding to *qi* (氣) deficiency. In particular, certain effects of rikkunshito on stomach pain and postprandial distension will enable clinical practitioners to more effectively treat functional dyspepsia in actual clinical settings. Rikkunshito is a Kampo product essential for persons living in modern society who suffer from functional dyspepsia, a psychophysiological disorder known to be difficult to treat. In this study, blood ghrelin concentrations did not change after rikkunshito administration. To elucidate the mechanism of rikkunshito, a formulation with tonic effects for spleen *qi* deficiency or *qi* deficiency affecting upper gastrointestinal tract symptoms, future studies will need to utilize biochemical measures such as biogenic markers and physiological markers including peristaltic movement of the gastrointestinal tract and secretory release of digestive enzymes.

12. Abstractor and date

Ushiroyama T, 31 March 2017.