11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Koide A. Effect and role of TJ-43: Rikkun-shi-to from the aspects of endoscopic findings and QOL improvement in GERD patients. *Medical Tribune Online* (*Digestive Disease Week: DDW*) 2005: 6-7 (in Japanese).

1. Objectives

To evaluate the efficacy of rikkunshito (六君子湯) combined with a proton pump inhibitor (PPI) for treating gastroesophageal reflux disease (GERD).

2. Design

Randomized controlled trial (RCT).

3. Setting

One general hospital, Japan.

4. Participants

Fifty-six patients with gastroesophageal reflux disease.

5. Intervention

Arm 1: oral administration of omeprazole (20 mg) plus TSUMURA Rikkunshito (六君子湯) Extract Granules (7.5 g), as the PPI + rikkunshito (六君子湯) group.
Arm 2: oral administration of omeprazole (20 mg), as the PPI alone group.

6. Main outcome measures

Endoscopic healing rates of reflux esophagitis and Gastrointestinal Symptom Rating Scale (GSRS) scores. The follow-up was scheduled at 8 weeks.

7. Main results

The endoscopic healing rates of reflux esophagitis at 8 weeks were not significantly different between the two groups. The PPI + rikkunshito group achieved significantly better scores on the following three GSRS domains: overall gastrointestinal symptoms, reflux, and abdominal pain.

8. Conclusions

Rikkunshito combined with PPI improves the quality of life (QOL) in GERD patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Rikkunshito-combined therapy resulted in further improvement of QOL in GERD patients, especially in those with endoscopy-negative GERD (non-erosive reflux disease: NERD). On this basis, the authors concluded that PPI + rikkunshito is effective for "the improvement of QOL, particularly in NERD patients who are unlikely to respond to PPI."

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008, 31 December 2013.