

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

Komatsuzaki O. Clinical effect of TSUMURA Rikkunshito on indefinite epigastric distress - comparison with a control agent, and assessment mainly based on the endoscopic findings and the histology of gastric mucosal biopsy specimens before and after the treatment - *. *Kampo Igaku (Kampo Medicine)* 1993; 17: 120-31 (in Japanese).

1. Objectives

To evaluate the efficacy of TSUMURA Rikkunshito (六君子湯) for treating indefinite complaints of epigastric distress, based on an analysis of gastric endoscopy findings and histological findings of gastric mucosal biopsy specimens before and after the treatment.

2. Design

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

3. Setting

Single institution (Tochigi National Hospital), Japan.

4. Participants

Thirty newly-presenting patients with gastritis who had 3 or more indefinite complaints of epigastric distress.

5. Intervention

Arm 1: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. before or between meals for 4 weeks (n=15).

Arm 2: treatment with Marzulene-S Granules (L-glutamine plus azulene) 2 g/day in three divided doses after meals for 4 weeks (n=15).

6. Main outcome measures

Measures of subjective symptoms, endoscopy findings, and histopathology.

7. Main results

Improvement in the subjective symptom score for abdominal bloating, global improvement score, and utility rating were significantly greater in arm 1 than in arm 2. Marked improvements in endoscopic or histopathologic findings were not observed.

8. Conclusions

TSUMURA Rikkunshito has beneficial effects on gastritis with epigastric distress and is a highly useful agent.

9. From Kampo medicine perspective

Stratified analysis of global improvement ratings revealed that improvements were greater in patients aged 61 or older than in those aged 60 or younger.

10. Safety assessment in the article

No adverse drug reactions occurred.

11. Abstractor's comments

This paper describes an evaluation of the clinical effect of TSUMURA Rikkunshito on indefinite epigastric distress, using outcome measures including gastric endoscopy findings and histological findings of gastric mucosal biopsy specimens before and after the treatment. In conclusion, marked changes in endoscopic or histopathologic findings were not observed, and the efficacy of rikkunshito for symptoms and gastrointestinal function was noted. Results of other measures were very similar to those from preceding studies.

12. Abstractor and date

Oikawa T, 19 September 2008, 1 June 2010.