

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**Reference**

Mizuno S, Yamagiwa K, Iwata M, et al. Effect of early treatment with TSUMURA Rikkunshito on gastrointestinal symptoms after resection of gastric cancer – focusing on reflux esophagitis -*. *Progress in Medicine* 2001; 21: 1366-7 (in Japanese). Ichushi Web ID: 2001269379 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the preventive effect of rikkunshito (六君子湯) on postoperative reflux esophagitis.

2. Design

Randomized controlled trial (RCT).

3. Setting

No description of the setting is available; the authors belong to the First Department of Surgery, Mie University School of Medicine, Japan.

4. Participants

Forty-six patients who underwent resection of stage I to II gastric cancer.

5. Intervention

Arm 1: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules, 7.5 g/day, every day from the start of postoperative oral intake in 25 patients.

Arm 2: no treatment in 21 patients.

6. Main outcome measures

1) Gastrointestinal symptoms including heartburn, dysphagia, nausea/vomiting, dyspepsia, and anorexia; 2) endoscopic findings based on the Los Angeles classification; and 3) mean length of postoperative hospital stay.

7. Main results

At postoperative week 2, gastrointestinal symptoms were observed in 7 untreated patients (33%) and 4 rikkunshito-treated patients (16%). All the symptoms occurred less commonly in the treated patients than in the untreated patients. At postoperative week 4, reflux symptoms and heavy stomach were each seen in only 1 (4%) patient in arm1, whereas reflux symptoms, heartburn, dyspepsia, and anorexia developed in 3 (14%), 1 (5%), 1 (5%), and 2 (10%), respectively, in arm 2. As for endoscopic findings at postoperative week 3, there were grade A in 2 patients (10%) and grade B in 1 (5%) in arm 2, but grade A in only 1 (5%) in arm 1. At postoperative week 6, grade A esophagitis was observed in 1 patient (5%) in arm 2, and none in arm 1. Mean length of postoperative hospital stay was not significantly different between the two arms (47 ± 13 days [arm 2] vs 39 ± 13 days [arm 1]), but a reduction of hospital days was noted.

8. Conclusions

Rikkunshito is highly effective not only for the treatment of reflux esophagitis after gastric cancer surgery, but also for the prevention of this disease.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Studies 1 and 2 are described in the article. Study 1 was conducted to examine the therapeutic effect of rikkunshito on postoperative reflux esophagitis. Rikkunshito at a daily dose of 7.5 g was administered between meals every day from the onset of symptoms in 7 patients with stage I-II gastric cancer. The authors reported that symptoms disappeared in most patients at week 4. But since Study 1 had no control group and provided no details such as evaluation criteria, it was excluded from this structured abstract. Only part of Study 2 was included. In Study 2, 'randomization into two groups' was reported, but the details were not clear. Also, other details, such as statistical procedures and methods of assessing subjective symptoms, were not provided. This study is clinically valuable, but most of the article, which is published in a conference record, lacks adequate descriptions. Thus, submission as an original article is desired.

12. Abstractor and date

Arai M, 1 April 2008, 1 June 2010.