

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

Uehara R, Isomoto H, Minami H, et al. Characteristics of gastrointestinal symptoms and function following endoscopic submucosal dissection and treatment of the gastrointestinal symptoms using rikkunshito. *Experimental and Therapeutic Medicine* 2013; 6: 1083-8. Pubmed ID: 24223626

1. Objectives

To evaluate the efficacy of rikkunshito (六君子湯) for gastrointestinal symptoms following endoscopic submucosal dissection (ESD) of early gastric cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital, Japan.

4. Participants

Thirteen patients who experienced upper gastrointestinal symptoms 6 to 8 days following stomach ESD. The patients had at least 3 of the following symptoms: epigastric pain, hunger pain, nausea, borborygmus, abdominal distension, eructation, and increased flatus assessed by the Gastrointestinal Symptom Rating Scale (GSRS) Questionnaire.

5. Intervention

Arm 1: Oral administration of proton pump inhibitor (PPI: rabeprazole) 10 mg b.i.d. and TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. for 8 weeks (n=8).

Arm 2: Oral administration of PPI for 8 weeks (n=5).

6. Main outcome measures

Gastric emptying (as assessed by the [¹³C]-labeled acetate breath test) at Weeks 0 and 8.

Scores for the following Gastrointestinal Symptom Rating Scale (GSRS) items: epigastric pain, hunger pain, nausea, borborygmus, abdominal distension, eructation, and increased flatus at Weeks 0, 4, and 8.

7. Main results

Gastric emptying was compared between subjects who underwent ESD and healthy volunteers rather than between Arms 1 and 2 and was significantly decreased in subjects who underwent ESD ($P<0.01$). Overall GSRS score was significantly decreased at Week 4 ($P<0.05$) and Week 8 ($P<0.01$) compared to Week 0 in Arm 1 but not Arm 2, and the GSRS subscale score for abdominal pain at Week 0 was significantly decreased at Week 8 in Arm 1 ($P<0.05$).

8. Conclusions

The combination of PPI and rikkunshito may alleviate symptoms (especially abdominal pain) in patients with upper gastrointestinal symptoms following ESD.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This RCT evaluated the efficacy of PPI + rikkunshito, which is believed to be effective for functional dyspepsia, in patients with upper gastrointestinal symptoms following ESD using change in subjective symptoms (GSRS score) as indicator. This study showed that gastric emptying was decreased following ESD but failed to measure gastric emptying after coadministration of rikkunshito and PPI. The authors suggested that the mechanism of this combined therapy, which improved abdominal pain following ESD, was associated with improved gastric emptying and increased secretion of ghrelin; however, this suggestion is based only on a literature review and was not verified. Future studies to evaluate the effects on frequency of postoperative bleeding (a complication of ESD) or time needed for mucosal defect (ulcer scarring) repair is anticipated. This structured abstract replaces a previous one (which was based on a convention abstract) and utilizes data from the original article.

12. Abstractor and date

Hoshino E, 31 December 2013; Motoo Y, 31 March 2017.