

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

Uehara R. An evaluation of gastrointestinal symptoms and gastric mobility after endoscopic submucosal dissection (ESD) and an investigation of the usefulness of Rikkunshito (TJ-43). *Dai 8 Kai Nippon Shokakan Gakkai Sokai Gakujutsu Syukai Workshop 4 PROCEEDING Jobu Shokaki Shojo to Kampo (Workshop 4 Proceedings of the 8th Annual Meeting of the Japanese Gastroenterological Association: Upper Gastrointestinal Symptoms and Kampo)* 2012: 16-7 (in Japanese).

1. Objectives

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

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital (Department of Gastroenterology and Hepatology, Nagasaki University), Japan.

4. Participants

Eleven patients with upper gastrointestinal symptoms following gastric ESD.

Patients with upper gastrointestinal symptoms were defined as patients with three or more symptoms based on the Gastrointestinal Symptom Rating Scale (GSRS) questionnaire: epigastric pain, hunger pain, nausea, borborygmus, bloat, belching, and flatus.

5. Intervention

Arm 1: oral administration of proton pump inhibitor (PPI) and TSJIMURA Rikkunshito (六君子湯) Extract Granules (7.5 g/day) (n=6).
Arm 2: oral administration of PPI (n=5).

6. Main outcome measures

Gastric emptying (^{13}C -labeled test) at 0 and 8 weeks.
GSRS questionnaire symptoms (epigastric pain, hunger pain, nausea, borborygmus, bloat, belching, and flatus) at 0, 4, and 8 weeks.

7. Main results

GSRS questionnaire symptoms at 0, 4, and 8 weeks after ESD showed no significant difference between arms 1 and 2, with no improvement compared to 0 weeks in both arms.

There was no improvement in any symptom at 4 or 8 weeks compared to 0 weeks in arm 2.

In arm 1, abdominal pain and overall score improved significantly at 4 and 8 weeks compared to 0 weeks (on GSRS subscales), and epigastric pain and hunger pain improved significantly at 8 weeks compared to 0 weeks.

8. Conclusions

Rikkunshito may be effective for relief of symptoms (epigastric pain and hunger 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 trial evaluated the usefulness of rikkunshito plus a PPI, which is considered effective for functional dyspepsia, in patients with upper gastrointestinal symptoms following ESD. Changes in gastric discharge function and subjective symptoms (GSRS) served as the indicators. Gastric emptying (usually decreased after ESD) was not improved by administering rikkunshito in addition to a PPI. Epigastric pain and hunger pain improvement after ESD resulting from the combined use of rikkunshito, as the authors assert, may be attributable to rikkunshito's adaptive relaxation effect or mucosal protective effect. Further study of these mechanisms are needed. The researchers will, hopefully, investigate ways of reducing the incidence of secondary hemorrhage or hastening the healing of ulcerated mucous membranes, two complications of ESD.

12. Abstractor and date

Hoshino E, 31 December 2013.

This structured abstract was retracted from EKAT, when EKAT Appendix 2015 was published.