11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References

Tominaga K, Sakata Y, Kusunoki H, et al. Rikkunshito simultaneously improves dyspepsia correlated with anxiety in patients with functional dyspepsia: A randomized clinical trial (the DREAM study). *Neurogastroenterology and Motility* 2018; 1-12. doi: 10.1111/nmo.13319 Pubmed ID: 29498457

1. Objectives

To evaluate the efficacy and safety of rikkunshito（六君子湯）in patients with functional dyspepsia

2. Design

Double-blind, randomized, controlled trial (DB-RCT)

3. Setting

Fifty-six hospitals, Japan

4. Participants

A total of 128 patients aged >20 years who had functional dyspepsia diagnosed according to the ROME III criteria, who were *Helicobacter pylori*-negative, and who had continuous symptoms after 2 weeks of placebo administration.

5. Intervention

Arm 1: oral administration of Rikkunshito（六君子湯）Extract Granules (manufacturer unknown) 2.5 g t.i.d. for 8 weeks (n=63)

Arm 2: oral administration of placebo 2.5 g t.i.d. for 8 weeks (n=65)

6. Main outcome measures

The primary endpoint was overall treatment efficacy (OTE). The secondary endpoints were the scores from the patient assessment of upper gastrointestinal disorders-symptom severity index (PAGI-SYM), Global overall symptom (GOS), Modified frequency scale for the symptoms of GERD (m-FSSG), Hospital anxiety and depression scale (HADS), and Short-form health survey-8 (SF-8).

7. Main results

During the study period, 2 patients in the rikkunshito group and 1 patient in the placebo group dropped out of the study. The OTE after 8 weeks of treatment in the rikkunshito group was “extremely improved” in 8.2% and “improved” in 29.5%, which were significantly higher compared with 1.8% and 21.1%, respectively, in the placebo group (P=0.019). After 8 weeks of treatment, the PAGI-SYM, GOS, m-FSSG, and HADS total scores were significantly decreased in the rikkunshito group compared with the placebo group (P=0.018, P =0.009, P =0.036, and P =0.027, respectively). The SF-8 did not show significant difference.

8. Conclusion

Rikkunshito alleviates gastrointestinal and psychological symptoms in *Helicobacter pylori*-negative patients with functional dyspepsia.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

Adverse events and adverse drug reactions occurred in 10.8% and 4.6%, respectively, of the patients in the rikkunshito group and 11.1% and 1.6%, respectively, of the patients in the placebo group.

11. Abstractor’s comments

This article describes an important clinical study that evaluated the efficacy of rikkunshito for functional dyspepsia. Knowing that assessment of subjective symptoms is relatively unlikely to show significant differences in RCTs, this study is particularly meaningful because it showed that a significantly higher percentage of patients in the rikkunshito group experienced relief of subjective symptoms. In addition, this study used existing scales to assess gastrointestinal and psychological symptoms, and demonstrated improvements in the rikkunshito group with significant differences, and so is a good reference for other physicians. Furthermore, since this study used Western medicine rather than Oriental medicine in diagnosing functional dyspepsia and evaluating the effect of rikkunshito on functional dyspepsia, the results from this study are usable by clinicians in Japan where Western medicine is predominant. Although clinical questions remain, such as whether rikkunshito should be continued or switched to another formula in patients with poor improvement after 8 weeks of treatment with rikkunshito, this article appears to be of great significance in that it provides a foundation for future clinical practices and studies.

12. Abstractor and date

Koike H, 1 June 2020.