11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Ohta Y, Nishioka M, Yamamoto Y, et al. Multicenter clinical evaluation of Kampo preparations for medical use in the treatment of gastritis (acute gastritis and acute exacerbation of chronic gastritis) - comparison with gefarnate as a control -*. *Shindan to Chiryo* (*Diagnosis and Treatment*) 1990; 78: 2935-46 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of rikkunshito (六君子湯) and hangeshashinto (半夏瀉心湯) for treating acute gastritis and acute exacerbation of chronic gastritis.

2. Design

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

3. Setting

Four university medical schools, including Ehime University School of Medicine (Third Department of Internal Medicine), Kagawa Medical School (Third Department of Internal Medicine), and Kochi Medical School (First Department of Internal Medicine), plus 13 hospitals (17 institutions in total), Japan.

4. Participants

Sixty-four patients who (i) visited one of the participating institutions between October 1986 and May 1987; (ii) had subjective symptoms such as abdominal pain and abdominal bloating; and (iii) were endoscopically confirmed to have gastritis lesion, diagnosed with gastritis (acute gastritis or acute exacerbation of chronic gastritis), and had indications for medical therapy. Patients with the following conditions were excluded: (i) peptic ulcer (except for scarring) or gastric cancer; (ii) so-called verrucous erosion with marginal elevations, or serious complications, particularly gastrointestinal disease (such as hepatobiliary disease); or (iii) known or suspected pregnancy.

5. Intervention

Arm 1: treatment with TSUMURA Rikkunshito Extract Granules (六君子湯) 2.5 g t.i.d. (n=20).
Arm 2: treatment with TSUMURA Hangeshashinto Extract Granules (半夏瀉心湯) 2.5 g t.i.d. (n=14).
Arm 3: treatment with gefarnate 100 mg t.i.d. (n=16).
Treatment duration was 4 weeks in principle; treatment was discontinued when symptoms disappeared during this period.

6. Main outcome measures

Subjective symptoms (nausea, anorexia, epigastric pain, abdominal bloating, abdominal discomfort, heartburn, belching, and fatigue), endoscopic findings (redness, erosion, edema, and hemorrhage), and laboratory findings (routine blood test, serum biochemistry, and urinalysis).

7. Main results

No statistically significant among-arm differences in subjective symptom improvement (5-point scale) and in endoscopic improvement (5-point scale) were found. The scores for both total endoscopic improvement and overall improvement (evaluated on the basis of subjective symptoms and endoscopic findings) tended to be slightly higher in arms 1 and 2 ($P<0.1$), but showed no statistically significant differences between each two arms. Overall usefulness (5-point scale) was assessed as “useful” or better in 80.0%, 85.7%, and 56.3% of patients, respectively, in arms 1, 2, and 3. The among-arm distribution of usefulness was significantly different ($P<0.05$). Multiple comparisons between two arms showed significantly higher usefulness score in arm 2 than in arm 3 ($P<0.05$).

8. Conclusions

Both TSUMURA Rikkunshito Extract Granules and TSUMURA Hangeshashinto Extract Granules result in improvements equivalent to or better than those obtained with gefarnate in the treatment of gastritis (acute gastritis and acute exacerbation of chronic gastritis); thus they are clinically effective and safe agents.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse drug reactions or laboratory abnormalities were not reported in any of the arms.

11. Abstractor’s comments

This report is clinically relevant in that the authors conducted a multicenter study comparing two types of Kampo preparations with an existing mucosal protectant and defining in detail the outcome measures. Recently, in western medicine, the idea of functional dyspepsia has been introduced and classification based on clinical symptoms prevails. In the future, the efficacy of Kampo formulas might be clarified using a symptoms-based method, in which subjective symptoms that respond specifically to each Kampo formula are identified by comparing responders and non-responders, and then selecting participants based on the specific symptoms. Future studies are expected.

12. Abstractor and date

Arai M, 20 October 2008, 1 June 2010, 31 December 2013.