

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

Kato S, Nakajima T, Matsuda T, et al. The effectiveness of the traditional Kampo medicine, “banxia houpu tang (hangekobokuto)” to respiratory disturbance by esophageal reflux disease. *Kampo to Saishin-Chiryō (Kampo & the Newest Therapy)* 2005; 14: 333-8 (in Japanese). Ichushi Web ID: 2006091322

1. Objectives

To evaluate the efficacy of hangekobokuto (半夏厚朴湯)-combined treatment in patients with respiratory symptoms associated with refractory gastroesophageal reflux disease (GERD).

2. Design

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

3. Setting

No description of the setting is available; the authors belong to the Department of Cardiology and Pneumology, Dokkyo Medical University, Japan.

4. Participants

Nineteen GERD patients whose digestive symptoms but not respiratory symptoms (including cough, sputum, throat discomfort, and mild dyspnea) were relieved by conventional western medical treatments. All patients had no history of smoking or respiratory disease.

5. Intervention

Arm 1: treatment with TSUMURA Hangekobokuto (半夏厚朴湯) Extract Granules (7.5 g/day) in 10 patients.

Arm 2: no treatment in 9 patients.

In arm 1, hangekobokuto (半夏厚朴湯) was administered in addition to the usual western medical treatment for 6 months, and then hangekobokuto (半夏厚朴湯) was discontinued. The course of respiratory symptoms was examined for a total of 12 months in both the hangekobokuto (半夏厚朴湯)-combined and no-treatment arms.

6. Main outcome measures

Cough, sputum, throat discomfort, and mild dyspnea.

7. Main results

The degree of improvement was evaluated on a 5-point scale. Respiratory symptoms were significantly improved after a month of treatment in arm 1, compared with arm 2 ($P<0.01$). This effect persisted up to 6 months after start of combined treatment ($P<0.01$) and 6 months after discontinuation of hangekobokuto ($P<0.01$).

8. Conclusions

Hangekobokuto relieves respiratory symptoms, including cough, sputum, throat discomfort, and mild dyspnea, that are unresponsive to western medical treatments in GERD patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Respiratory or ear-nose-throat symptoms are reported to occur in 30–50% of GERD patients, depending on the literature. Western medical treatments combine proton pump inhibitors, H₂ blockers, or stomachics, with theophylline formulations, expectorants, antitussives, erythromycin antibiotics, or inhaled steroids. In some patients, however, these treatments fail to improve these symptoms. This study can be praised for examining these clinically difficult-to-treat patients. The study method has several problems including failure to measure inter-subject variability of GERD scores evaluated according to the Los Angeles classification, small sample size, and lack of a safety and adverse drug reactions assessment.

12. Abstractor and date

Arai M, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.