

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

Morita T. Evaluation of rikkunshito on esophageal motor function\*. *Nikkei Medical (Supplement)* 2010; 8: 27 (in Japanese).

**1. Objectives**

To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.

**2. Design**

Randomized controlled crossover trial (RCT - cross-over).

**3. Setting**

No description (the author is from the Second Department of Internal Medicine, Shimane University), Japan.

**4. Participants**

Twenty healthy volunteers.

**5. Intervention**

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days, then placebo for 7 days (number of participants not specified).

Arm 2: placebo for 7 days then TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days (number of participants not specified).

**6. Main outcome measures**

Saliva amount, salivary epidermal growth factor (EGF), salivary bicarbonate concentration.

**7. Main results**

Rikkunshito caused no significant change in saliva amount, salivary EGF, or salivary bicarbonate concentration.

**8. Conclusions**

Rikkunshito increases lower esophageal sphincter (LES) resting internal pressure in healthy people, but does not affect saliva excretion.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

Saliva dilutes refluxed acid and neutralizes bicarbonate, while EGF appears to aid repair of esophageal mucous cells. Decreased saliva excretion in conditions including gastroesophageal reflux, Sjogren's syndrome, diabetes, old age, and stress facilitate the onset of reflux esophagitis. This trial was conducted on the assumption that increases in saliva excretion, and therefore in EGF and bicarbonate, by rikkunshito will improve gastroesophageal reflux disease (GERD). But the study found no significant effect on these factors, which at this point suggests that rikkunshito's main mechanism of action is the increase in LES pressure. The subjects in this study were healthy volunteers, so a further study might verify that the improvement of GERD by rikkunshito is due to increased saliva excretion. To confirm the mechanism, participants with reduced saliva excretion (e.g., elderly people, diabetics, or Sjögren's syndrome sufferers) should be compared to participants with normal saliva excretion to find the differences among them.

**12. Abstractor and date**

Motoo Y, , 31 December 2012.