

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

Iturrino J, Camilleri M, Wong BS, et al. Randomized clinical trial: the effects of daikenchuto, TU-100, on gastrointestinal and colonic transit and anorectal and bowel function in female patients with functional constipation. *Alimentary Pharmacology and Therapeutics* 2013; 37: 776-85. CENTRAL ID: CN-00853558, Pubmed ID: 23451764

1. Objectives

To evaluate the efficacy and safety of daikenchuto (大建中湯) in the treatment of functional constipation.

2. Design

Randomized controlled trial (RCT).

3. Setting

Mayo Clinic, U.S.A. (single institution).

4. Participants

Forty-five subjects with functional constipation recruited from October 2010 to November 2012.

5. Intervention

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules po 2.5 g t.i.d for 4 weeks (n=15).
Arm 2: TSUMURA Daikenchuto (大建中湯) Extract Granules po 5 g t.i.d for 4 weeks (n=15).
Arm 3: Placebo (n=15).

6. Main outcome measures

Gastrointestinal transit, rectal compliance, rectal sensation thresholds, gastrointestinal motility in response to anal sphincter pressures and bowel movement status, changes in psychosensory symptoms associated with constipation, and quality of daily life.

7. Main results

Gastrointestinal motility was not significantly increased by arm 1 and arm 2 compared to arm 3. There was no difference in main outcome measures between arm 1 and arm 2. In arm 2, daikenchuto lowered the rectal sensation thresholds for the first bowel movement and gas sensation ($P = 0.045$ and 0.024 , respectively).

8. Conclusions

In women with functional constipation, daikenchuto may increase the rectal sensation threshold for bowel movement but has no therapeutic effect on gastrointestinal motility, stool softness, frequency of stools, psychosensory symptoms, or quality of life. The mechanism of action of daikenchuto remains to be elucidated in clinical settings.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Although daikenchuto produced adverse reactions such as headache and abdominal pain, no differences in adverse reactions were noted among the groups and daikenchuto was safe and well tolerated.

11. Abstractor's comments

This excellent study measured defecation sensation in the rectum associated with intestinal motility and defecation behavior in women with functional constipation by using various objective, physiological examination methods, in an attempt to elucidate the clinical efficacy of daikenchuto. The study revealed that 5 g/dose (15 g/day) of daikenchuto does not affect gastrointestinal motility or rectal sensation. However, it lowers the thresholds for bowel movement and gas sensation in the rectum, a finding which will contribute a great deal to the conduct of future clinical studies of daikenchuto. Daikenchuto is not widely used for the treatment of functional constipation, but has been shown to promote gastrointestinal motility in *in vitro* experiments. The present study may be the driving force for the elucidation of how daikenchuto-related sub-ileus can be prevented. I hope verification will be obtained from a different point of view or based on a study protocol that involves the *sho* (証, pattern) for daikenchuto.

12. Abstractor and date

Ushiroyama T, 6 June 2015