

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

Horiuchi A, Nakayama Y, Tanaka N. Effect of traditional Japanese medicine, Daikenchuto (TJ-100) in patients with chronic constipation. *Gastroenterology Research* 2010; 3: 15165.

**1. Objectives**

To evaluate the effects of daikenchuto (大建中湯) in combination for chronic constipation patients taking sennoside.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One hospital, Japan.

**4. Participants**

Twenty-two patients with chronic constipation presenting with abdominal pain and bloating and treated for more than 3 months by taking sennoside (24660 mg/day). Participants' stool frequency was less than three times a week when not taking sennoside. Colonoscopy revealed no abnormality, and participants had no history of abdominal surgery.

**5. Intervention**

Arm 1: Sennoside 24 to 60 mg/day with TSUMURA Daikenchuto (大建中湯) Extract Granules 7.5 g/day for 6 weeks (n=14).

Arm 2: Sennoside 24 to 60 mg/day with TSUMURA Daikenchuto (大建中湯) Extract Granules 15 g/day for 6 weeks (n=8).

**6. Main outcome measures**

Abdominal bloating (visual analogue scale), abdominal pain (visual analogue scale), Gastrointestinal Symptoms Rating Scale (GSRS), Gas Volume Score (GVS).

**7. Main results**

Abdominal bloating scores decreased significantly in both arms from 55 before intervention to 20 after four weeks of intervention in arm 1 ( $P=0.006$ ) and from 69 to 35 in arm 2 ( $P=0.007$ ). Abdominal pain scores decreased significantly from 32 to 9 after four weeks in arm 2 ( $P=0.02$ ). GSRS scores also decreased significantly in both arms after four weeks, from 2.6 to 2.2 in arm 1 ( $P=0.002$ ), and from 2.8 to 2.3 in arm 2 ( $P=0.008$ ). GVS scores decreased significantly in both arms after six weeks, from 0.049 to 0.040 in arm 1 ( $P=0.02$ ), and from 0.042 to 0.036 ( $P=0.016$ ) in arm 2.

**8. Conclusions**

Daikenchuto alleviates abdominal pain and bloating in chronic constipation patients taking a stimulant laxative.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

There were no adverse reactions.

**11. Abstractor's comments**

This study suggests that when taken in combination with sennoside, daikenchuto alleviates abdominal pain and bloating in chronic constipation patients. However, the study only makes before/after comparisons, not between-group comparisons. Daikenchuto is a prescription that warms the middle abdominal region and treats *kyosho* (虚証, deficiency patterns) (温中補虚), so it warms the gastrointestinal tract. On the other hand, the active constituent in senna leaf (番泻葉) is sennoside, which resolves heat in the stomach and intestines and promotes intestinal peristalsis. In Kampo medical terms, these drugs are used for the opposing pattern. Hopefully, researchers will conduct a trial that compares sennoside + daikenchuto to control groups including placebo and daikenchuto alone. Lastly, if each participant's *sho* (証, pattern) had been identified in this comparative study, light might have been shed on the pathological conditions for which daikenchuto is indicated.

**12. Abstractor and date**

Okabe T, 31 December 2012.