

## 21. Others

**Reference**

Saida Y, Sumiyama Y, Nagao J, et al. Dai-kenchu-to, a herbal medicine, improves precolonoscopy bowel preparation with polyethylene glycol electrolyte lavage: results of a prospective randomized controlled trial. *Digestive Endoscopy* 2005; 17: 50-3. CENTRAL ID: CN-00575598, Ichushi Web ID: 2006000780

**1. Objectives**

To evaluate the efficacy of daikenchuto (大建中湯) combined with polyethylene glycol solution (PG solution) in pretreatment for large bowel endoscopy.

**2. Design**

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

**3. Setting**

None (authors belong to the 3<sup>rd</sup> Department of Surgery, Toho University School of Medicine), Japan.

**4. Participants**

Two-hundred and eighty-five patients who underwent total large bowel endoscopy between January and December 2001, gave informed consent to participate in this trial, and remained after excluding those under 18 years old, pregnant women, and other ineligible patients.

**5. Intervention**

Arm 1: combination of PG solution and TSUMURA Daikenchuto (大建中湯) Extract Granules (oral administration of 2.5 g each at 12:00 and 21:00 on the day before and 7:00 on the day of large bowel endoscopy) (n=144).

Arm 2: PG solution alone (n=141).

Endoscopy was performed by an experienced specialist.

**6. Main outcome measures**

Frequency of defecation on the day of endoscopy, time until defecation, presence or absence of abdominal pain, abdominal score, presence or absence of nausea, nausea score, pretreatment score, and time required to reach the ileocecal area.

**7. Main results**

The PG solution/daikenchuto combination group and PG solution group defecated  $7.9 \pm 3.1$  times and  $7.7 \pm 3.6$  times, respectively, and required  $3.3 \pm 1.6$  hr and  $3.0 \pm 1.5$  hr until defecation, respectively. The incidence of abdominal pain (score) was 17% ( $0.17 \pm 0.38$ ) and 15% ( $0.15 \pm 0.35$ ), respectively, and the incidence of nausea (score) was 24% ( $0.28 \pm 0.55$ ) and 21% ( $0.21 \pm 0.43$ ), respectively. Thus, there were no significant between-group differences in these parameters. Pretreatment score was significantly improved in the PG solution/daikenchuto combination group ( $0.28 \pm 0.52$  vs  $0.81 \pm 0.77$  in the PG solution group;  $P < 0.01$ ). The time required to reach the ileocecal area was also significantly reduced in the PG solution/daikenchuto combination group ( $6.4 \pm 3.6$  min vs  $7.3 \pm 4.0$  min in the PG solution group;  $P = 0.04$ ).

**8. Conclusions**

PG solution/daikenchuto pretreatment for large bowel endoscopy is a more patient-friendly effective method for facilitating insertion (compared with pretreatment with PG solution alone) and does not increase the level of uncomfortable symptoms such as abdominal pain, nausea, and frequent defecation.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This randomized controlled trial demonstrated that daikenchuto combined with PG solution is superior to PG alone in the preparation of the large intestine for endoscopy. This study has a large sample size and is well designed, but fails to explain pretreatment score and abdominal pain score. It has been presented in a previous report "Saida Y. The 15th Surgery and Kampo Medicine Study Meeting 1. Efficacy of combined use of daikenchuto in pretreatment for large bowel endoscopy - 6 prospective studies - . *Progress in Medicine* 2005; 25: 3058-9 (in Japanese)."

**12. Abstractor and date**

Arai M, 10 March 2007, 30 October 2007, 1 June 2010, 31 December 2013.