

**21. Others****Reference**

Saida Y, Takase M, Okumura C, et al. Efficacy of combined use of shakuyakukanzoto in pretreatment for large bowel endoscopy – prospective randomized trial\*. *Nihon Daicho Kensa Gakkai Zasshi (Journal of the Japan Society of Colon Examination)* 2003; 20: 34-7 (in Japanese). Ichushi Web ID: 2005123565

**1. Objectives**

To evaluate the efficacy of shakuyakukanzoto (芍薬甘草湯) combined with polyethylene glycol solution (PEG) 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 Department of Colon and Rectal Surgery, Tohokamagaya Hospital), Japan.

**4. Participants**

Seventy patients who were scheduled to undergo large bowel endoscopy between November 2000 and March 2001 and gave informed consent to participate in this trial.

**5. Intervention**

Arm 1: oral administration of shakuyakukanzoto (芍薬甘草湯) (2.5 g t.i.d.) starting from lunchtime on the day before endoscopy (n=37).

Arm 2: non-treatment (n=33).

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 and severity of abdominal pain associated with pretreatment, presence or absence and severity of nausea, pretreatment condition (residue), and time required to reach cecum.

**7. Main results**

Frequency of defecation and time until defecation were  $6.9 \pm 2.5$  times and  $234 \pm 36$  min, respectively, in arm 1 and  $7.6 \pm 3.4$  times and  $171 \pm 30$  min, respectively, in arm 2, showing reduced frequency and extended time until defecation in arm 1, although there were no significant differences between arms. The incidence and score of abdominal pain were 11% and  $0.6 \pm 0.4$ , respectively, in arm 1 and 12% and  $0.5 \pm 0.4$ , respectively, in arm 2, showing no difference between arms. Nausea was more prevalent in arm 1 with the incidence of 33%, compared with 12% in arm 2, although there was no difference in nausea score between arms. Pretreatment score and time required to reach cecum were  $0.9 \pm 0.8$  and  $7.9 \pm 5.4$  min, respectively, in arm 1 and  $0.7 \pm 0.8$  and  $7.9 \pm 5.5$  min, respectively, in arm 2, showing no difference between arms.

**8. Conclusions**

Shakuyakukanzoto combined with PEG tends to slightly suppress the cleansing of the bowel needed prior to large bowel endoscopy and may induce nausea, suggesting its ineffectiveness in such pretreatments.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

To achieve adequate intestinal lavage in preparation for large intestine endoscopy, a large amount of PEG has to be swallowed. In terms of efficacy and patient satisfaction, however, currently available pretreatments are not always useful. Focusing on this issue, the present study is meaningful. To further enhance the quality of this clinical research, however, the control should be a placebo that has no effect on bowel motility rather than no treatment. With no other useful concomitant drugs available, it is hoped that new drugs and useful approaches will be investigated.

**12. Abstractor and date**

Arai M, 23 February 2007, 30 October 2007, 1 June 2010.