

**2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)****Reference**

Akamaru Y, Takahashi T, Nishida T, et al. Effects of daikenchuto, a Japanese herb, on intestinal motility after total gastrectomy: a prospective randomized trial. *Journal of Gastrointestinal Surgery* 2015; 19: 467-72.

**1. Objectives**

To evaluate the efficacy and safety of daikenchuto (大建中湯) for promoting peristalsis in patients with reduced intestinal peristalsis after total gastrectomy

**2. Design**

Randomized controlled trial (RCT)

**3. Setting**

Department of Gastroenterological Surgery, University Hospital and surgical departments of 7 affiliated hospitals

**4. Participants**

Patients with gastric cancer scheduled for a total gastrectomy. Subjects were 20 to 80 years old, and had histologically confirmed stage I, II, or III gastric cancer without previous cancer treatment or past history of other cancers. One hundred patients underwent D2 lymphadenectomy (with spleen preservation), Roux-en-Y reconstruction, and R0 surgery (no remaining cancer).

**5. Intervention**

Arm 1: The intervention group had 51 patients who received oral administration of TSUMURA Daikenchuto Extract Granules 2.5 g with 20 mL of tepid water three times per day. The administration was started after the operation when oral intake was allowed, and continued for 3 months.

Arm 2: The control group had 49 patients who only received 20 mL of tepid water three times per day.

**6. Main outcome measures**

Gut motor function (time to first bowel movement, the frequency of stools, and the properties of stools according to the Bristol stool form scale [BSFS]), the gas volume score (GVS) based on abdominal roentgenograms, the quality of life (QOL) (Gastrointestinal Symptom Rating Scale [GSRS]), and the occurrence of postoperative ileus.

**7. Main results**

Because of the non-curative intent of the operation, changes in operative procedures, complications, withdrawal of informed consent, etc., 10 patients in Arm 1 and 9 patients in Arm 2 dropped out, reducing the number of subjects for analysis to 41 in Arm 1 and 40 in Arm 2. There were statistically significant differences between Arm 1 and Arm 2 in the number of stools ( $1.1 \pm 0.6$  vs  $0.8 \pm 0.4$ ,  $P=0.037$ ) and the properties of stools (BSFS  $3.7 \pm 0.8$  vs  $3.1 \pm 0.8$ ,  $P=0.041$ ) during hospitalization. The GVS were lower in Arm 1 than Arm 2 at day 7 ( $78 \pm 25$  vs  $108 \pm 35\%$ ,  $P<0.05$ ), 1 month ( $70 \pm 26$  vs  $95 \pm 49\%$ ,  $P<0.05$ ), and 3 months ( $62 \pm 33$  vs  $90 \pm 38\%$ ,  $P<0.05$ ) after the operation. There were no statistically significant differences in the GSRS, which indicates the QOL, or the occurrence of postoperative ileus (one case in Arm 1, or 2.4%, and two cases in Arm 2, or 5.0%) between the groups.

**8. Conclusions**

Daikenchuto promotes intestinal peristalsis to improve stool properties and intestinal gas.

**9. From Kampo medicine perspective**

Not mentioned.

**10. Safety assessment in the article**

There were no adverse events associated with daikenchuto.

**11. Abstractor's comments**

In order to promote intestinal peristalsis after surgery, daikenchuto is routinely administered in clinical practice. Therefore, this study, which proved its efficacy, is very important. Although daikenchuto is called "a Japanese herb" in the title of the paper, it is not a single herb and should be called "a Japanese herbal medicine". If the study had been done blindly, which is hard to do, the results could have been more reliable. The difference in the occurrence of postoperative ileus might have become significant if the sample size had been larger. Moreover, the authors should have known that the usual dose of daikenchuto is 15 g per day when they designed the RCT. Different doses might have produced different results.

**12. Abstractor and date**

Tsuruoka K, 20 April 2017