

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

Yaegashi M, Otsuka K, Itabashi T, et al. Applying a Kampo medication to lower gastrointestinal tract surgery\*. *Shokaki Geka (Gastroenterological Surgery)* 2013; 36: 1315-24.

**Yaegashi M, Otsuka K, Itabashi T, et al. Daikenchuto stimulates colonic motility after laparoscopic-associated colectomy. *Hepato-Gastroenterology* 2014; 61: 85-9. CENTRAL ID: CN-00991603, Pubmed ID: 24895799**

**1. Objectives**

To evaluate the effectiveness of daikenchuto (大建中湯) for perioperative intestinal paralysis following laparoscopic colon cancer surgery.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One center: Department of Surgery, Iwate Medical University, Japan.

**4. Participants**

Fifty-four cases of laparoscopic colon cancer surgery (aged between 43 and 89 years).

**5. Intervention**

Arm 1: Daikenchuto (大建中湯) (manufacturer unknown) 7.5 g/day two days before surgery then from the first day after surgery until discharge from hospital (n=27, aged 51 to 83 years).

Arm 2: Intestinal disorder medication two days before surgery then from the first day after surgery until discharge from hospital (n=27, aged 43 to 89 years).

**6. Main outcome measures**

Time until first flatus and until bowel movement. Time to the first toleration of solid food (50% rice gruel diet). Colonic transit time with radiopaque markers.

**7. Main results**

Since 1 patient in arm 1 and 2 patients in arm 2 dropped out of the study, the efficacy analysis set included 26 and 25 patients in arm 1 and arm 2, respectively. Greater acceleration of first flatus and bowel movement from post-operative extubation was observed in arm 1 compared to arm 2 ( $P<0.05$ ). Time to toleration of the first solid food was similar between the arms. Colonic transit time was significantly shorter in arm 1 (no description of P-value). White blood cell count and CRP showed no significant difference between arms.

**8. Conclusions**

Daikenchuto is effective for accelerating improvement of intestinal paralysis following laparoscopic surgery.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

No adverse drug reactions were observed.

**11. Abstractor's comments**

This paper is a randomized controlled trial (RCT) investigating the effectiveness of daikenchuto in improving intestinal paralysis after laparoscopic surgery. Previous papers have reported early administration of daikenchuto to be effective in improving gastrointestinal dysfunction, however, this paper suggests even greater efficacy by commencing administration before surgery. Although 7.5 g/day was selected in this RCT as the standard dose of daikenchuto, the authors should have recognized that the usual dose is 15.0 g/day. In the DISCUSSION, the authors state that doses depending on body weight should have been considered if daikenchuto had dose-dependent effects. However, since body weight-dependent dosing is impossible in actual clinical settings, an RCT selecting the dose of 15.0 g/day should be conducted at first. A larger clinical trial evaluating the effectiveness of daikenchuto and its administration timing in the perioperative period is anticipated in the future.

**12. Abstractor and date**

Okabe T, 6 June 2015; Motoo Y, 31 March 2017