

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

**Reference (20090877A)**

Yoshikawa K. Evaluation of anti-inflammatory efficacy of daikenchuto\*. *Dai 5 Kai Nippon Shokakan Gakkai Sokai Gakujutsu Syukai (5th Annual Meeting of the Japanese Gastroenterological Association) (Workshop 5)* 2009: 9-10.

**1. Objectives**

To evaluate the reduction in the number of days to postoperative flatulence and the anti-inflammatory efficacy of daikenchuto (大建中湯) in patients who underwent laparotomy for large intestine carcinoma.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One hospital (Tokushima University Hospital).

**4. Participants**

Thirty postoperative patients with large intestine carcinoma.

**5. Intervention**

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules postoperatively (dose and duration of treatment were not specified); Arm 2: no treatment. Primary outcome: postoperative flatulence. Secondary outcomes: postoperative abdominal pain, postoperative nausea and vomiting, postoperative fever, postoperative wound healing, postoperative infection, postoperative ileus, postoperative respiratory infection, postoperative urinary tract infection, postoperative delirium, postoperative mortality, and postoperative quality of life.

**6. Main outcome measures**

In addition to the primary outcome, postoperative white blood cell count, lymphocyte count, and levels of C-reactive protein (CRP), β-D-glucan, and *Candida* antigen were determined before and 1, 3, 5, and 7 days after the operation.

**7. Main results**

There were no between-arm differences in age, sex, age at onset of operation, blood loss, or duration of their hospitalization, including lymphocyte count, CRP level. There was no significant between-arm difference in the white blood cell count, β-D-glucan level, or *Candida* antigen level. CRP level (5.1±2.3 vs. 7.7±4.7;  $P<0.05$ ) and the number of days to postoperative flatulence (1.7±0.4 vs. 2.9±0.8;  $P<0.05$ ) were significantly lower in arm 1 than in arm 2 on postoperative day 3.

**8. Conclusions**

Daikenchuto is useful in promoting flatulence and inhibiting inflammation after surgery for large intestine carcinoma.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

None.

**11. Abstractor's comments**

Reduction in the time to resumption of intestinal peristalsis and inhibition of postoperative inflammation (CRP) after surgery for large intestine carcinoma in order to reduce medical costs and hospital stay are interesting issues. To explain the early postoperative anti-inflammatory effect of daikenchuto, the author referred to daikenchuto-mediated inhibition of inflammatory cytokine production, intestinal mucosal villous damage, and bacterial translocation demonstrated in a fasted rat model. Further analysis of the effects of daikenchuto on the general condition (appetite, sleep, bowel movement, hot flushes, etc.) of postoperative patients will be needed before treatment of all patients with daikenchuto is deemed appropriate.

**12. Abstractor and date**

Hoshino E, 1 June 2010.

This structured abstract was retracted from EKKAT, when EKKAT Appendix 2014 was published.