

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

Yoshikawa K, Shimada M, Nishioka M, et al. The effects of the Kampo medicine (Japanese herbal medicine) "Daikenchuto" on the surgical inflammatory response following laparoscopic colorectal resection. *Surgery Today* 2012; 42: 646-51. Ichushi Web ID: 2013248005, Pubmed ID: 22202972

**1. Objectives**

To evaluate the anti-inflammatory effects of daikenchuto (大建中湯) on patients with colorectal cancer following laparoscopic resection.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One center: Tokushima University Hospital, Japan.

**4. Participants**

Thirty patients with colorectal cancer following laparoscopic resection.

**5. Intervention**

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules (7.5 g/day) for seven days from the day after surgery (n=15).

Arm 2: no administration of daikenchuto (大建中湯) (n=15).

**6. Main outcome measures**

Number of days to first flatus and number of days to discharge after surgery were recorded and measurements were taken before surgery and on days 1, 3, 5, and 7 after surgery for body temperature, heart rate, white blood cell count, lymphocyte count, C-reactive protein (CRP),  $\beta$ -D-glucan, and Candida antigen.

**7. Main results**

Mean age was significantly lower in arm 1 than arm 2. The number of days to first flatus was significantly lower in arm 1 ( $1.8 \pm 0.5$ ) than arm 2 ( $2.7 \pm 0.5$ ). Only on the third day of hospitalization, CRP was significantly lower in arm 1 ( $4.6 \pm 0.6$ ) than arm 2 ( $8.3 \pm 1.1$ ). Body temperature was significantly lower in arm 1 ( $36.2 \pm 0.4$ ) than arm 2 ( $36.9 \pm 0.6$ ). There was no significant difference between arms for number of days to discharge after surgery, heart rate, white blood cell count,  $\beta$ -D-glucan, and Candida antigen.

**8. Conclusions**

Administering daikenchuto for seven days from the day after laparoscopic colorectal cancer surgery is useful for inhibiting inflammation and promoting flatus.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

If it were possible to inhibit the inflammatory response (CRP) and shorten the period of intestinal paralysis through some form of intervention after colorectal surgery, there would be a decrease in hospitalization periods and in the need for treatment for complications, which would be useful from the point of view of controlling medical costs; however, hospitalization periods did not decrease in this study. The authors of this study chose patients who underwent laparoscopic surgery for their study with an aim to demonstrate that daikenchuto has an anti-inflammatory effect after surgery with low invasiveness. The inflammation inhibitory action mechanisms of daikenchuto soon after surgery that the authors listed include 1) promotion of intestinal motility through increased release of acetylcholine from cholinergic nerves mediated by Japanese Pepper (sansho), 2) the subsequent inhibition of enteric bacterial growth, 3) increase in dose-dependent intestinal tract blood flow mediated by Processed Ginger (kankyo), and 4) the inhibition of bacterial translocation and homeostasis maintenance in the intestinal epithelium mediated by inhibition of the production of inflammatory cytokines such as IFN- $\gamma$ , IL-6, and TNF- $\alpha$  attributable to daikenchuto, observed in rats. While inhibiting inflammation after abdominal surgery might be useful for recovery from surgical invasion, it is liable to be disadvantageous from the point of view of defense. And the multifaceted effects of Kampo medications are a merit as well as a demerit. There needs to be careful verification of whether surgeons' current habit of indiscriminately prescribing daikenchuto for long periods after abdominal surgery is valid or not. Furthermore, while the authors have published a study undertaken at the same time under the same protocols in conference proceedings (*Proceedings of the 5<sup>th</sup> Annual Meeting of the Japanese Gastroenterological Association* 2009: 9-10), the results of that paper differ from the results of this one. This appears to be due to differences in some of the cases enrolled in the study (for that reason, the structured abstract, which had been included in the previous version of Evidence Reports of Kampo Treatment [EKAT], was excluded from EKAT Appendix 2014 [added to the list of excluded abstracts]).

**12. Abstractor and date**

Hoshino E. 6 June 2015