

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**11. Gastrointestinal, HepatoBiliary-Pancreatic Diseases****Reference**

Kono T, Shimada M, Nishi M, et al. Daikenchuto accelerates the recovery from prolonged postoperative ileus after open abdominal surgery: a subgroup analysis of three randomized controlled trials. *Surgery Today* 2019; 1-8. Pubmed ID: 30805720, UMIN ID: UMIN 000026292

1. Objectives

To analyze whether daikenchuto (大建中湯) accelerates the recovery from prolonged postoperative ileus after open abdominal surgery.

2. Data source

Three randomized controlled trials (RCTs) of JFMC39 (colon), JFMC40 (liver), and JFMC42 (gastric cancer) that assessed the effect of daikenchuto on prolonged postoperative ileus.

3. Study selection

A secondary analysis was conducted on the three multicenter RCTs supported by the Japanese Foundation for Multidisciplinary Treatment of Cancer (JFMC) assessing the effect of daikenchuto on prolonged postoperative ileus after open abdominal surgery.

4. Data extraction

Of a total of 862 randomized patients with colon, liver, or gastric cancer who underwent open abdominal surgery, 122 patients were excluded from the respective studies for ineligibility or other reasons (i.e., 50 patients in JFMC39 [colon] including 32 patients who were considered to be ineligible for continuing the study, 22 patients in JFMC40 [liver] including 15 patients who were considered to be ineligible for continuing the study, and 50 patients in JFMC42 [stomach] including 15 patients who were considered to be ineligible for continuing the study). The remaining 740 patients were eligible for efficacy analysis. Of these patients, 410 patients with no bowel movement before the first meal after surgery (main analysis cohort), and the remaining 330 patients (non-main analysis cohort) were included in the subgroup analysis.

5. Main results

Main analysis cohort

Arm 1: Daikenchuto (大建中湯) 15 g (n=214)

Arm 2: Placebo 15 g (n=196)

Non-main analysis cohort

Arm 1: Daikenchuto 15 g (n=158)

Arm 2: Placebo 15 g (n=161)

In the main analysis cohort, the time from the end of surgery to the first bowel movement was significantly shorter in the daikenchuto group. In the non-main analysis cohort, the time from the end of surgery to the first bowel movement did not differ between the two groups.

6. Conclusions

Daikenchuto significantly accelerated the recovery from prolonged postoperative ileus following open abdominal surgery.

7. From Kampo medicine perspective

None.

8. Safety assessment in the article

None.

9. Abstractor's comments

The key point of this subgroup analysis of 3 RCTs is that it showed the effectiveness of daikenchuto in patients with impaired intestinal motility after open abdominal surgery. On the basis of the primary endpoint, that is, the time from the end of surgery to the first bowel movement, daikenchuto was effective for prolonged postoperative ileus.

10. Abstractor and date

Nakata H, 31 October 2019.