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

Reference

Ota M. A Randomized controlled trial of perioperative daikenchuto for colorectal cancer surgery*. *Progress in Medicine* 2012; 32: 618–9 (in Japanese). MOL, MOL-Lib

1. Objectives

To verify inhibition of inflammatory cytokine production and post-operative enhanced reactivation of intestinal function by daikenchuto (大建中湯) in colorectal cancer patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

Yokohama City University Hospital, Japan.

4. Participants

Eighteen colorectal cancer patients scheduled for surgery.

5. Intervention

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules 15.0 g/day for nine days[1)] (n=8).
Arm 2: no administration of daikenchuto (大建中湯) (n=10).

[1)] Daikenchuto was started two days before surgery, then restarted on the second day after surgery and continued until the eighth day.

6. Main outcome measures

Period between initial flatus and defecation, postoperative hospital stay (days), incidence of postoperative ileus, and postoperative white blood cell (WBC) count, C-reactive protein (CRP) level, interleukin (IL)-6 level, tumor necrosis factor (TNF)-α level, and natural killer (NK) cell activity (days 1, 3, and 7)

7. Main results

The period to initial flatus lasted one to two days in most cases and there was no between-arm difference. The period to initial defecation was significantly shorter in arm 1. There was no significant difference in the occurrence of ileus (two patients in arm 1, no patients in arm 2). CRP level tended to be decreased in patients with body mass index (BMI) under 23 in arm 1 but not in patients with a BMI over 23 in both groups. Between-group difference in IL-6 level, TNF-α level, or NK activity was not significant.

8. Conclusions

Daikenchuto enhances postoperative intestinal reactivation.

9. From Kampo medicine perspective

The tendency for reduced CRP among patients with lower BMI suggests that daikenchuto may be effective for patients with *kyo-sho* (虚証, deficiency pattern).

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study was an attempt to clinically prove through evidence provided by RCT that perioperative daikenchuto enhances postoperative intestinal reactivation in colorectal cancer patients. However, the trial design (which tries to avoid bias related to the surgical procedure [laparoscopic vs. open] and disease location [colon vs. rectum]) introduces potential randomization problems. In addition, the actual sample size was 18 patients rather than the target sample size of 30; the significant difference in period until initial defecation was very small; two patients in the daikenchuto group but no patient in the no administration group suffered ileus; the tendency for decreased CRP level in patients with a BMI under 23 was very slight; and generally differences in laboratory test results were not significant. This leaves the undeniable impression that the evidence for the conclusion is fairly weak. Hopefully the author will recruit a larger sample population and include types of surgery and pathological findings (colorectal cancer invasion depth, etc.) in the analysis.

12. Abstractor and date

Motoo Y, 31 December 2013.