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

References

Watanabe K. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery.* *Kampo Igaku* (*Science of Kampo Medicine*) 2010; 34: 346–7 (in Japanese). MOL, MOL-Lib

Fujii S. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery.* *Progress in Medicine* 2011; 31: 468–9 (in Japanese).

1. Objectives

To evaluate the effectiveness and safety of daikenchuto (大建中湯) soon after colorectal cancer surgery.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Center for Gastroenterological Disease, Yokohama City University, Japan.

4. Participants

Participants received surgery (cur A resection) for colon cancer or sigmoid colon cancer between September 2009 and August 2010 (n=151). They were all over 20 years old, with performance status 0 or 1, and ability to eat and drink 2 days after surgery. No participants were asked for their laparotomy history or type of abdominal surgery (laparotomy or laparoscopic surgery). Participants with a history of emergency surgery, double cancer, or colostomy were excluded.

5. Intervention

Arm 1: daikenchuto (大建中湯) group (manufacturer not identified): 5 g t.i.d. (n=57).
Arm 2: mosapride (Gasmotin®) group: 5 g t.i.d. (n=54).
Arm 3: control group: no treatment (n=40).

6. Main outcome measures

Recovery of intestinal movement after surgery (period until both gas and stool passed), number of days in hospital after surgery, anti-inflammatory action (leucocytes, C-reactive protein [CRP] level), intestinal obstruction incidence, adverse events.

7. Main results

The period until gas was passed was significantly shorter in arm 1 and arm 2 than in arm 3 (2.6 days in arm 1 [P= 0.001], 2.8 days in arm 2 [P= 0.036], and 3.4 days in arm 3). No significant difference in the period until stool was passed was evident among the groups (arm 1, 3.4 days; arm 2, 3.8 days; arm 3, 3.8 days). The incidence of intestinal obstruction was lower but not significantly lower in arm 1 (arm 1, 1.8%; arm 2, 5.8%; arm 3, 10%). No among-group difference was observed in the leucocyte count, but the decrease in CRP in arm 1 was significant from the third day (P<0.05), suggesting that daikenchuto had anti-inflammatory effect. The number of days spent in the hospital after surgery was 8.7 in arm 1, 10.8 in arm 2, and 10.1 in arm 3, so hospital stay was the shortest for arm 1, and significantly shorter than that of arm 2 (P= 0.045). Comparison with arm 3 yielded a P-value of 0.061.

8. Conclusions

Patients treated with daikenchuto soon after colorectal cancer surgery recover intestinal movement more rapidly. The results suggest that daikenchuto may shorten post-surgery hospital stay and decrease the incidence of intestinal obstruction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Rash was observed in one participant in the daikenchuto group, and liver dysfunction in one participant in the mosapride group, however, the causal relation to the medications remains unclear.

11. Abstractor's comments

This abstract summarizes the article by Fujii (2011). The trial is clinically significant for suggesting the effectiveness of Daikenchuto. The two references listed above reported on the same study. Watanabe's article (2010) appears to be an interim paper. This trial is not an RCT in the strict sense of the word because treatment was assigned on an alternate month basis. The study seems to offer the possibility of subanalysis, so further work is anticipated.

12. Abstractor and date

Tsuruoka K, 31 December 2012.