Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine. 2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)

Reference

Omori K. Prospective randomized controlled study of daikenchuto for postoperative dysmotility after total gastrectomy^{*}. *Progress in Medicine* 2012; 32: 614-5 (in Japanese). MOL, MOL-Lib

1. Objectives

To evaluate the effectiveness and safety of daikenchuto (大建中湯) for postoperative bowel dysmotility after gastric cancer and total gastrectomy.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital surgery department, Japan.

4. Participants

One-hundred patients (age range: 44–80 years) with curability A/B who underwent total gastrectomy (Roux-en Y) for gastric cancer.

5. Intervention

Arm 1: daikenchuto (manufacturer not specified) (7.5 g/day) for three months (n=51). Arm 2: lukewarm water (20 mL) for three months (n=49).

6. Main outcome measures

Frequency of post-surgical complications (post-surgical ileus), gastrointestinal symptom quality of life (QOL, measured on the gastrointestinal symptom rating scale [GSRS]), bowel regularity, intestinal gas.

7. Main results

After 15 participants dropped out, the data for 85 participants were evaluated. There was no significant difference in the incidence of ileus, with one case in arm 1 and three in arm 2. Improvement in constipation was greater in arm 1 than arm 2 at one month and three months. Apart from that, there was no significant between-group difference in gastrointestinal symptom QOL (GSRS). Bowel regularity during hospitalization was significantly higher in arm 1 (1.1 ± 0.6) than arm 2 (0.7 ± 0.4) (P<0.05). Stools were significantly softer in arm 1 than arm 2. Intestinal gas had decreased significantly in arm 1 compared to arm 2 at one week, one month, and three months after surgery.

8. Conclusions

Daikenchuto contributes to early improvement in intestinal dysmotility in patients following total gastrectomy and is effective in reducing post-operative complaints.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse events were reported.

11. Abstractor's comments

This study was a randomized clinical trial that evaluated the effectiveness and safety of daikenchuto for postoperative bowel dysmotility after gastric cancer and total gastrectomy. The authors suggest that daikenchuto is effective for early improvement of intestinal dysmotility following surgery. The study confirms a reduction in the area of intestinal gas (an objective indicator) in the daikenchuto group at one week after surgery, as well as subjective symptoms including an increase in bowel-movement frequency.

12. Abstractor and date

Okabe T, 31 December 2013.