Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

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

Reference

Nishimura G. Evaluation of clinical efficacy of hochuekkito in improving nutritional/immune status in patients with surgery for large intestine carcinoma^{*}. *Progress in Medicine*. 2009; 29: 84-85. MOL, MOL-Lib

1. Objectives

To evaluate the efficacy of 1-week preoperative treatment with hochuekkito (補中益気湯) for improving pre- and postoperative nutritional status and immune function in patients scheduled to undergo laparotomy for large intestine carcinoma.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

One hospital (Kanazawa Red Cross Hospital), Japan.

4. Participants

Twenty patients scheduled to undergo laparotomy for large intestine carcinoma.

5. Intervention

Arm 1: TSUMURA Hochuekkito (補中益気湯) Extract Granules at a dose of 2.5 g t.i.d. from 7 days to 1 day before the operation (n=10).

Arm 2: not treated (n=10).

6. Main outcome measures

Height, body weight (body mass index [BMI]), white blood cell count, and levels of C-reactive protein (CRP), total protein, albumin, prealbumin, and immunological parameters (IL-6, CD4, CD8) were determined before and after administration preoperatively and 1, 3, and 7 days postoperatively.

7. Main results

One patient in arm 1 dropped out. The remaining 19 patients (9 in arm 1 and 10 in arm 2) were included in the analysis. There was no between-arm difference in the age, sex, affected site, duration of the operation, blood loss, or percentage of patients who received blood transfusion and no significant between-arm difference in body weight (BMI), white blood cell count, CRP, total protein, or albumin. Mean prealbumin level tended to be higher in arm 1 than in arm 2 from the day before surgery to 7 days after surgery, with a significant difference observed only 3 days after surgery (P=0.02). IL-6 tended to be lower in arm 1 than in arm 2 on postoperative day 1.

8. Conclusions

Preoperative treatment with hochuekkito may be useful for early recovery from surgery for large intestine carcinoma.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

Adverse events: one patient in arm 1 dropped out because he/she refused the treatment due to "no Kampo medicine was accepted constitutionally."

11. Abstractor's comments

Administering hochuekkito for 1 week prior to surgery for large intestine carcinoma to improve perioperative nutritional/immune status and reduce complications and thereby to reduce hospital stay and medical costs is an interesting issue. In revitalization therapy, hochuekkito is an *hozai* (補剤; formulations with tonic effects) that is focused on "*qi* (気虚, *qi* deficiency)" and on improving anorexia, general malaise, sleep disorder, etc. Prealbumin is a short-lived protein that reflects recent protein intake. Hochuekkito may have acted by reducing the patient's anxiety and thus preventing loss of appetite before surgery. Appetite, sleep, bowel movement, etc., which were not followed in this study, should also be monitored. It would be desirable to confirm the usefulness of hochuekkito in randomized controlled trials using other *hozai* (juzentaihoto and ninjin'yoeito) or anxiolytics as controls.

12. Abstractor and date

Hoshino E, 1 June 2010.