

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

Iwagaki H, Saito S. Regulation of post-operative systemic inflammatory response syndrome (SIRS) by preoperative administration of hochuekkito (a Japanese herbal medicine). *Nihon Toyo Igaku Zasshi (Kampo Medicine)* 2010; 61: 78–83 (in Japanese with English abstract). Ichushi Web ID: 2010110656
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1. Objectives

To evaluate the efficacy of preoperative administration of hochuekkito (補中益気湯) for postoperative systemic inflammatory response syndrome (SIRS) in gastric/colon cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

Okayama University Hospital and 8 related facilities, Japan.

4. Participants

Fifty-one patients undergoing laparotomy for advanced gastric/colon cancer in the period between February and December 2004.

5. Intervention

Medication taken for 7 consecutive days preoperatively to the day before surgery.

Arm 1: hochuekkito (補中益気湯) extract granules (manufacturer not indicated) 2.5 g t.i.d. (n=24).

Arm 2: no administration (n=27).

6. Main outcome measures

Serum cortisol level and soluble interleukin (IL)-2 receptor (sIL-2R) level immediately before and at 1 day after the operation; white blood cell (WBC) count and differential WBC count before and 1 and 7 days after the operation; C-reactive protein (CRP) level before and 1, 3, and 7 days after the operation; body temperature/pulse rate from the day before to 14 days after the operation; use of antibiotics until 14 days after the operation.

7. Main results

The analysis population consisted of 48 patients (after 2 and 1 patient dropped out in arm 1 and arm 2, respectively). There was no significant between-arm difference in preoperative serum cortisol level, but a tendency toward lower preoperative sIL-2R level in the hochuekkito group ($P=0.08$). The percent decline in cortisol level from preoperative baseline to postoperative day 1 value was significantly greater in arm 1 than in arm 2 ($P=0.04$), while there was no significant between-arm difference in the decline in sIL-2R level, WBC count, differential WBC count, or CRP level before and 1 and 7 days after the operation. The pre- to postoperative declines in mean body temperature and mean pulse rate were significantly greater in arm 1 ($P=0.0002$ and $P=0.03$, respectively). Fewer patients used second-line antibiotics postoperatively in the hochuekkito group than in the control group ($P=0.05$).

8. Conclusions

Preoperative administration of hochuekkito significantly suppresses the postoperative inflammatory response to surgical wounding.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study is significant because it demonstrates by RCT that preoperative 1-week administration of hochuekkito significantly suppresses postoperative SIRS, while focusing on the characteristics of Kampo medicine for treating *mibyō* (未病, subclinical state). The use of antibiotics, mentioned in the last section of the results, was said to be “significantly different between arms” even though $P=0.05$. The criterion for significance, indicated in the text, was $P < 0.05$. Preoperative administration of hochuekkito reduced postoperative complications and duration of hospitalization, which is medically and economically beneficial. Furthermore, administration of hochuekkito may raise the awareness of patients and prepare them for surgery.

12. Abstractor and date

MotooY, 30 December 2010.