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

Reference

Saito S, Iwagaki H, Kobayashi N, et al. Effects of a Japanese herbal medicine (TJ-41) on surgical stress of patients with gastric and colorectal cancer*. *Nihon Rinsho Geka Gakkai Zasshi* (*Journal of Japan Surgical Association*) 2006; 67: 568-74 (in Japanese). Ichushi Web ID: 2006114494, J-STAGE

1. Objectives

To evaluate whether preoperative administration of hochuekkito (補中益気湯) relieves surgical stress in patients with gastric or colorectal cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Gastroenterological Surgery, Transplant and Surgical Oncology, Okayama University, and six other institutions, Japan.

4. Participants

Forty-eight patients who underwent surgery for gastric (n=10) or colorectal (n=38) cancer.

5. Intervention

Arm 1: treatment with TSUMURA Hochuekkito (補中益気湯) Extract Granules 2.5 g, t.i.d. for 1 week prior to surgery (n=22).

Arm 2: no preoperative treatment (n=26).

6. Main outcome measures

The levels of cortisol, soluble tumor necrosis factor receptor (sTNF-R), and soluble interleukin-2 receptor (sIL-2R) measured right before surgery and on postoperative day 1; total and differential white blood cell counts measured preoperatively and postoperatively at days 1 and 7; C-reactive protein level measured preoperatively and postoperatively at days 1, 3, and 7; postoperative course of body temperature and pulse rate; length of postoperative stay; the number of patients who received therapeutic antibiotics after surgery.

7. Main results

There were no significant between-arm differences in total and differential white blood cell counts, CRP level, and rates of increase in sTNF-R and sIL-2R from before to after surgery. The rate of increase in cortisol from before to after surgery was significantly lower in arm 1. The body temperature from postoperative day 6 was significantly lower in arm 1. The pulse rate on postoperative days 6 and 7 was significantly lower in arm 1. The number of patients who received therapeutic antibiotics after surgery was significantly smaller in arm 1 (3/22) than in arm 2 (11/22).

8. Conclusions

Preoperative administration of TSUMURA Hochuekkito Extract Granules reduces the response to surgical stress and may be helpful for accelerating postoperative recovery.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse events: no adverse drug reactions occurred in arm 1.

11. Abstractor's comments

The authors postulate that preoperative administration of hochuekkito improves quality of life, helps control body temperature and heart rate, and reduces therapeutic administration of antibiotics in patients during postoperative recovery, and thus may lead to reduction of medical costs. They also suggest that the mechanism underlying these effects may involve Kampo medicine-induced attenuation of the increase in cortisol blood level. The principle of this treatment is similar to that of "immunonutrition," which involves omega-3 fatty acids, arginine, and nucleic acids. These approaches attempt to reduce postoperative surgical complications by means of preoperative nutritional supplementation. Cancer patients before surgery are in a state of *qikyo* (気虚, qi deficiency) with various anxieties, and at the same time in a relatively mild state of *kekkyo* (血虚, blood deficiency) if they are operable. Hochuekkito and other comparable *hozai* (補剤; formulations with tonic effects) seem to be suitable for these patients. The investigation of hochuekkito combined with the immunonutritional approach and further elucidation of the mechanism are anticipated in the future.

12. Abstractor and date

Hoshino E, 15 March 2009, 1 June 2010, 31 December 2013.