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

Reference

Yamada T. Clinical study of juzen-taiho-to administration for postoperative esophageal carcinoma, gastric carcinoma, and colorectal carcinoma – Influence of surgical intervention and postoperative chemotherapy on cell mediated immunity–. *Wakan Iyaku Gakkaishi* (*Journal of Medical and Pharmaceutical Society for WAKAN-YAKU*) 1992; 9: 157-64 (in Japanese with English abstract).

1. Objectives

To evaluate the effect of juzentaihoto (十全大補湯) on the cell-mediated immunity of postoperative patients with esophageal, gastric, or colorectal cancer.

2. Design

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

3. Setting

A university hospital (Kyorin University Hospital), Japan.

4. Participants

One hundred seventy-four postoperative patients with esophageal, gastric, or colorectal cancer.

5. Intervention

Arm 1: TSUMURA Juzentaihoto (十全大補湯) Extract Granules 7.5 g/day beginning 2 weeks after surgery (n=75).
Arm 2: no treatment (n=99).
Patients in arms 1 and 2 who received anticancer agents within 1 month after surgery were considered to be separate groups, i.e., combination therapy groups (cf., arm 3 and arm 4), and their data were analyzed separately.
Arm 3: TSUMURA Juzentaihoto (十全大補湯) Extract Granules 7.5 g/day + anticancer agents beginning 2 weeks after surgery (n=49).
Arm 4: no treatment with juzentaihoto (十全大補湯) + anticancer agents (n=55).
The duration of treatment was 6 months.

6. Main outcome measures

Hemoglobin, white blood cell count, lymphocyte count, and levels of serum albumin, CD3, CD4, CD8, phytohemagglutinin (PHA) lymphocyte proliferation, and NK-cell activity.

7. Main results

In patients undergoing total gastrectomy in arm 3, hemoglobin and red blood cell count increased significantly and the white blood cell count decreased significantly. Immune function as indicated by PHA-induced lymphocyte proliferation and NK-cell activity was enhanced in patients with esophageal cancer or total gastrectomy in arm 3.

8. Conclusions

Juzentaihoto postoperatively administered for treatment of esophageal, gastric, or colorectal cancer may act as a biological response modifier (BRM).

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

This study evaluates the change in cell-mediated immunity in response to postoperative administration of juzentaihoto in patients with esophageal, gastric, or colorectal cancer. The data suggest that juzentaihoto may act as a BRM. This study included a variety of cancers, operative procedures, and medical conditions. Investigation (including survival analysis) with a larger sample size in limited populations is expected.

12. Abstractor and date

Oikawa T, 19 September 2008, 6 January 2010, 1 June 2010.