

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

Suzuki S, Abe R, Nomizu T, et al. Effect of Juzentaihoto (TJ-48) on leukopenia in patients receiving cancer chemotherapy\*. *Progress in Medicine* 1995; 15: 1968-71 (in Japanese). Ichushi Web ID: 1996098925

**1. Objectives**

To evaluate the effects of juzentaihoto (十全大補湯) on leukopenia in patients receiving cancer chemotherapy.

**2. Design**

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

**3. Setting**

Four university and community hospitals, Japan.

**4. Participants**

Ninety patients who received chemotherapy for cancer.

**5. Intervention**

Arm 1: treatment with TSUMURA Juzentaihoto (十全大補湯) Extract Granules 7.5 g/day (n=47 patients, including 17 with gastric, 20 with colorectal, and 10 with breast cancer).

Arm 2: no treatment (n=43 patients, including 16 with gastric, 19 with colorectal, and 8 with breast cancer).

Duration of treatment: 12 months.

**6. Main outcome measures**

Leukocyte count was measured before and after 1, 2, 3, and 4 weeks of treatment, then monthly for 12 months. The frequency and time course of leukopenia (defined as a leukocyte count less than 4,000 cells/m<sup>3</sup>) were also evaluated during the follow-up.

**7. Main results**

Leukocyte counts were not significantly different between the two arms. Significantly fewer patients developed leukopenia (<4,000mm<sup>3</sup>) in arm 1 (30 patients) than in arm 2 (38 patients). The onset of leukopenia was significantly delayed and the time from onset to nadir was significantly increased in arm 1. There was no between-arm difference in the time from nadir to recovery. Juzentaihoto had a beneficial effect on leukopenia in gastric or colorectal cancer patients, but not in breast cancer patients.

**8. Conclusions**

Juzentaihoto delays the onset of leukopenia and also increases the time from onset to nadir in patients receiving chemotherapy for gastric or colorectal cancer.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This paper demonstrates the usefulness of prophylactic administration of juzentaihoto for leukopenia, which is one of the serious adverse reactions to cancer chemotherapy in patients with gastric or colorectal cancer. The authors explored the factors influencing the effects in detail and demonstrated that juzentaihoto delayed the onset of leukopenia, increased the time from onset to nadir, but had no influence on the time to recovery, thereby reducing the number of patients who developed leukopenia. Recently, even more severe cases of leukopenia have become treatable with granulocyte colony-stimulating factor (G-CSF). Nevertheless, oral administration of juzentaihoto as a prophylaxis is valuable. Although the evaluation based on cancer type failed to find an effect in breast cancer patients, it was a secondary objective of this study and therefore reexamination in those patients is needed. Also, studies taking into account the Kampo concept of *sho* (証, pattern) are anticipated.

**12. Abstractor and date**

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010.