

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

Tanaka Y, Hashimoto S. Effects of TSUMURA Juzentaihoto on various complaints occurring as adverse reactions during radiotherapy\*. *JAMA* (Japanese version) 1988; (6) suppl: 70-1 (in Japanese).

**Hashimoto S, Tanaka Y. Adverse reactions to cancer radiotherapy\*. *Sanfujinka no Sekai (World of Obstetrics and Gynecology)* 1990; 42 suppl: 176-84 (in Japanese).**

**1. Objectives**

Efficacy and safety of juzentaihoto (十全大補湯) for reducing adverse reactions during cancer radiotherapy.

**2. Design**

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

**3. Setting**

Multi-center study involving 9 institutions: 6 university hospitals and 3 community hospitals, Japan.

**4. Participants**

Eighty-three patients who underwent radiotherapy of the chest or abdomen (the irradiated area was about 100 cm<sup>2</sup> and exposure dose was 50–60 Gy).

**5. Intervention**

Arm 1: TSUMURA Juzentaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. (n=43).

Arm 2: no treatment (n=40).

**6. Main outcome measures**

Subjective symptoms: anorexia, general malaise, nausea and vomiting, and diarrhea.

White blood cell, red blood cell, and platelet counts, and blood biochemical values.

**7. Main results**

Before radiotherapy, there was no significant between-group difference. For anorexia, a trend towards improvement in the treatment group was observed after 4–6 weeks and the difference was significant after 5 weeks ( $P<0.05$ ). There were also between-group differences in general malaise after 4 weeks, in nausea and vomiting after 5 weeks, and in diarrhea after 3–5 weeks. There were no differences in white blood cell, red blood cell, and platelet counts, and in blood biochemical values.

**8. Conclusions**

Juzentaihoto for adverse reactions during cancer radiotherapy reduced the symptoms of anorexia, general malaise, nausea and vomiting, and diarrhea.

**9. From Kampo medicine perspective**

This study did not take into account *sho* (証, pattern), according to the related article indicated below.

**10. Safety assessment in the article**

Juzentaihoto has few adverse effects, according to the related article.

**11. Abstractor's comments**

The present study was a multicenter RCT based on a previous single-center open trial and controlled trial examining the effect of juzentaihoto for GI side-effects during cancer radiotherapy. The study is valuable in that it was carefully planned for many years.

Although almost the same number of patients assigned to each group, the study included more women (male:female ratio = 1:3). Therefore, further investigation is required to determine whether the observed improvements in symptoms are related to the treatment of only female-related cancer or all cancers. Investigation taking into consideration *sho* to amplify the effect is also expected in the future.

The paper by Tanaka et al (1988) described the allocation method using sealed envelopes, which is not stated in the main article by Hashimoto et al (1990), and also described that mainly patients with breast or uterine cancer were included.

**12. Abstractor and date**

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010, 31 December 2013.