

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

Yamada T. Randomized controlled trial of the efficacy of Juzentaihoto (TJ-48) combined with oral 5-FU for gastric cancer*. *Progress in Medicine*. 2004; 24: 2746-7 (in Japanese)

1. Objectives

To evaluate the efficacy of juzentaihoto (十全大補湯; TJ-48) combined with oral 5-FU as postoperative adjuvant chemotherapy in patients with surgically treated gastric cancer.

2. Design

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

3. Setting

Fifteen hospitals associated with Gifu University, Japan.

4. Participants

Ninety-four patients with surgically treated gastric cancer satisfying the following 8 criteria were included: (1) curability A or B; (2) no serious complications; (3) no preoperative treatment; (4) no double or multiple cancer; (5) WBC $\geq 3,000/\text{mm}^3$, Plt $\geq 70,000/\text{mm}^3$, total protein $\geq 6.0\text{g/dL}$, AST/ALT $\leq 60\text{ IU/L}$, and urinary protein (-), before the start of chemotherapy; (6) no possibility of pregnancy; (7) performance status of grade 0 or 1; (8) receipt of consent to participate in the study from patient or family member.

5. Intervention

Arm 1: combination therapy group; continuous treatment with 5-FU tablets (200 mg/day) combined with TSUMURA Juzentaihoto (十全大補湯) Extract Granules (TJ-48; 7.5 g/day) for 2 years starting 2 weeks after surgery; 43 patients.

Arm 2: monotherapy group; continuous treatment with 5-FU tablets (200 mg/day) for 2 years starting 2 weeks after surgery; 51 patients.

6. Main outcome measures

Five-year survival rate, 5-year survival rate by clinical stage.

7. Main results

Five-year survival rate was 74.3% in arm 1 and 73.5% in arm 2, indicating no significant difference between arms. By clinical stage, patients with stage I or II had 2-year and 5-year survival rates of 92% and 90%, respectively, in arm 1 (n=42), and 91% and 83%, respectively, in arm 2 (n=35), indicating no significant difference between arms. In contrast, patients with stage III or IV had 2-year and 5-year survival rates of 22% and 0%, respectively, in arm 1 (n=9), and 87% and 25%, respectively, in arm 2 (n=8), with median survival of 35.1 months in arm 2 and 14.2 months in arm 1, demonstrating significantly extended survival of patients treated with juzentaihoto.

8. Conclusions

Combination of juzentaihoto with oral 5-FU is effective for patients with surgically treated stage III or IV gastric cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

The finding that the combination with juzentaihoto extends the postoperative survival of patients with surgically treated gastric cancer is clinically very impressive. The adverse drug reactions (ADRs) associated with this anticancer treatment are also of interest. Also, some information on study design (such as blinding) is lacking, making further evaluation difficult. Publication of the original paper is awaited.

12. Abstractor and date

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.