

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

Kosaka A, Hojyo M, Osaku M, et al. The value of TSUMURA Juzentaihoto (TJ-48) in reducing adverse effects of anticancer drugs from the perspective of QOL improvement*. *Progress in Medicine* 1993; 13: 1072-9 (in Japanese).

Kosaka A, Kamiya T, Sumiyama M, et al. Usefulness of TSUMURA Juzentaihoto (TJ-48) for reducing adverse effects of anticancer drugs and improving QOL*. *Progress in Medicine* 1994; 14: 2259-64 (in Japanese).

1. Objectives

To evaluate the efficacy of juzentaihoto (十全大補湯) for reducing adverse effects and improving quality of life (QOL) in postoperative patients undergoing chemotherapy (tegafur-uracil [UFT] 4 capsules/day) for gastric, colorectal, or breast cancer (curative resection/non-curative resection).

2. Design

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

3. Setting

Twelve hospitals, Japan.

4. Participants

Two-hundred and eighty-four postoperative patients undergoing chemotherapy for at least 3 months for gastric, colorectal, or breast cancer.

5. Intervention

Arm 1: UFT 4 capsules/day + TSUMURA Juzentaihoto (十全大補湯) Extract Granules 7.5 g/day (n=124).

Arm 2: UFT 4 capsules/day alone (no administration of juzentaihoto (十全大補湯)) (n=127).

Arm 3: surgical excision alone (n=33)

6. Main outcome measures

Presence or absence of adverse drug reactions to the anticancer drug. QOL, evaluated using an interview sheet preoperatively, and 2 weeks, 1, 3, and 6 months postoperatively.

7. Main results

Adverse drug reactions to UFT: arm 1 < arm 2 for colorectal cancer; arm 1 = arm 2 for gastric cancer; arm 1 > arm 2 for breast cancer (data not analyzed statistically, no definite differences).

QOL: significantly improved in breast cancer patients only for disease symptoms 2 weeks postoperatively and only for adverse drug symptoms and social life 6 weeks postoperatively and not significantly improved in patients with any other cancer for any symptoms, mood, and social life at any time point.

8. Conclusions

Juzentaihoto reduces the number of adverse drug reactions and improves QOL in postoperative patients on chemotherapy (UFT 4 capsules/day) for gastric, colorectal, or breast cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse events were vomiting and difficulty taking medications in 1 and 3 patients with colorectal cancer, respectively, in Arm 1.

11. Abstractor's comments

The authors wrongly conclude that combination of juzentaihoto with the anticancer drug (UFT) reduces adverse drug reactions and improves QOL, since there was almost no statistically significant difference. The conclusion should be guided by the correct interpretation of the results. Since the study failed to demonstrate the hypothesized usefulness of juzentaihoto, the authors should have discussed in the paper why postoperative patients with cancer receiving UFT did not respond to juzentaihoto. The possible reasons include: patients with cancer on postoperative chemotherapy may not be indicated for a *hozai* (補劑, formulations with tonic effects); may have a *sho* (証, pattern) indicated for a *hozai* other than juzentaihoto; or may respond to different *hozai* depending on cancer type. Even before that, this study should have begun with confirmation that the participants suffered from adverse drug reactions to UFT, had reduced QOL, did not respond to western medicine, and required treatment with Kampo medicine.

There is another report by the same first author of a study limited to one center (Kosaka et al [1993]). This study was then expanded to a multicenter trial with a larger sample size and produced similar results.

12. Abstractor and date

Hoshino E, 28 April 2009, 1 June 2010, 31 December 2013.