Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

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

References

Sasaki K, Ezoe E, Araya J, et al. Effects of Kampo medicine on the immune functions in gastrointestinal gastroenteric cancer patients– utility from the perspective of immunity. *Kampo to Saishin-chiryo (Kampo & the Newest Therapy)* 2006; 15: 9-14 (in Japanese).

Sasaki K, Takasaka H, Furuhata T, et al. Effect of Kampo medicine on the cancer chemotherapy of cancer. *Geka Chiryo (Surgical Therapy)* 2007; 97: 504-10 (in Japanese). MOL, MOL-Lib

1. Objectives

To evaluate the clinical efficacy of juzentaihoto (十全大補湯) for the prevention of postoperative recurrence of colorectal cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

The First Department of Surgery of Sapporo Medical University and other institutions (their names, unspecified), Japan.

4. Participants

One hundred and sixty-eight patients (mean age, 65 years) with stage II or III colorectal cancer who received curative resection and adjuvant chemotherapy between July 2001 and March 2005.

5. Intervention

Arm 1: treatment with oral 5-FU and juzentaihoto (十全大補湯) (manufacturer, not specified) 7.5 g/day, n=86.

Arm 2: treatment with oral 5-FU, n=82.

6. Main outcome measures

Recurrence rate, time to recurrence, and survival time.

7. Main results

Mean postoperative follow-up was 38.6 months. Recurrence rate for patients with stage II disease was slightly, though not significantly, more favorable in arm 1 (6.9%) than in arm 2 (14.0%). Mean times to recurrence were 18.2 months in arm 1 and 16.9 months in arm 2. The 3-year recurrence-free survival rate was slightly, though not significantly, better in arm 1: 92.2% in arm 1 and 85.9% in arm 2 for patients with stage II disease, and 67.5% and 62.9%, respectively, for patients with stage III disease.

8. Conclusions

Juzentaihoto may have a metastasis-suppressive effect, but since these are interim reports, the follow-up is still ongoing.

9. From Kampo medicine perspective None.

10. Safety assessment in the article None.

11. Abstractor's comments

These two papers are interim reports on a multicenter clinical study that evaluated the clinical efficacy of juzentaihoto for the prevention of postoperative recurrence of colorectal cancer. The data from slightly less than 100 patients in each arm were analyzed. At this point, no clear difference is observed between the juentaihoto-treated arm and the control arm, although the outcomes tend to be slightly more favorable in the former. A final report is anticipated. This abstract summarized mainly data from the second, recently published, paper mentioned above.

12. Abstractor and date

Oikawa T, 31 December 2008, 1 June 2010.