#### **Evidence Reports of Kampo Treatment**

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

Adachi I. Supporting therapy with shi quan da bu tang in advanced breast cancer patients. *Biomedical Research* 1990; 11 suppl: 25–31.

Adachi I, Watanabe T, Chen JY, et al. Supportive therapy of oriental medicine for patients with advanced breast cancer. *Gan to Kagaku Ryoho* (*Japanese Journal of Cancer and Chemotherapy*) 1989; 16: 1538–43 (in Japanese with English abstract). CENTRAL ID: CN-00060398, Pubmed ID: 2730051, Ichushi Web ID: 1990185338

Adachi I. Juzen-taiho-to as a supporting therapy in advanced breast cancer. Biotherapy 1989; 3: 782–8. Ichushi Web ID: 1991039494

### 1. Objectives

To evaluate the efficacy of supportive therapy with juzentaihoto (十全大補湯) for advanced breast cancer patients.

### 2. Design

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

### 3. Setting

Not mentioned (Dr. Adachi belongs to the faculty of the National Cancer Center), Japan.

### 4. Participants

A total of 119 patients were included in the study. Inclusion criteria: 1) advanced breast cancer with metastasis; 2) 6-month or longer survival expected; 3) no history of gastrointestinal surgery; 5) ability to take drugs orally; 6) no cancer other than breast cancer; and 7) use of anticancer drugs for breast cancer but no use of other Kampo medicines.

### 5. Intervention

Arm 1: chemotherapy + hormone therapy + juzentaihoto (十全大補湯) (manufacturer unknown) 5-7.5 g (n=58).

Arm 2: chemotherapy + hormone therapy (n=61).

### 6. Main outcome measures

Significance test using Kaplan-Meier survival curve.

### 7. Main results

There were no significant differences in survival and biochemistry between the control group and juzentaihoto group; however, when the juzentaihoto group was stratified by Kampo diagnostic criteria not mentioned), a significant difference was noted in survival (P<0.05).

## 8. Conclusions

If used appropriately, supportive therapy with juzentaihoto is effective for patients with breast cancer.

## 9. From Kampo medicine perspective

None.

### 10. Safety assessment in the article

Within 2 weeks of treatment initiation, edema and skin pruritus appeared in 2 patients, one of whom withdrew from treatment.

# 11. Abstractor's comments

This study evaluated the efficacy of juzentaihoto as supportive therapy for breast cancer. The conclusion that use of juzentaihoto as supportive therapy should be based on Kampo diagnosis is very suggestive. Considering the significance of this point, the rationale for diagnostic criteria for juzentaihoto-indicated patients should be specified.

### 12. Abstractor and date

Nakata H, 1 January 2009, 1 June 2010, 31 December 2013.