#### **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)

#### Reference

Inui H, Yamagata T, Minakata Y, et al. Prevention of side effects during lung cancer chemotherapy by Hochuekki-to. *Kampo to Saishin-chiryo (Kampo & the Newest Therapy)* 1993; 2: 56–60 (in Japanese).

### 1. Objectives

To evaluate the preventive and relieving effect of hochuekkito (補中益気湯) on general malaise in patients undergoing chemotherapy (including cisplatin for 5 days) for advanced primary lung cancer.

### 2. Design

Cross over randomized controlled trial (RCT-cross over).

### 3. Setting

One hospital, Japan.

#### 4. Participants

Nine patients with advanced (stage III–IV) lung cancer (small cell [n=4] and non-small cell [n=5]) who underwent gross curative resection and postoperative cisplatin + etoposide and postoperative cisplatin + mitomycin + vindesine, respectively.

### 5. Intervention

Arm 1: hochuekkito (補中益気湯) (manufacturer unknown) 2.5 g t.i.d. in combination in the first course and anticancer drugs alone in the second course.

Arm 2: anticancer drugs alone in the first course and hochuekkito (補中益気湯) (manufacturer unknown) 2.5 g/day in combination in the second course.

Comparison between anticancer drugs alone and hochuekkito (補中益気湯) (manufacturer unknown) 2.5 g t.i.d. in combination.

#### 6. Main outcome measures

Subjective symptoms (appetite, mood, sleep, general malaise, daily life, and face scale) with and without hochuekkito rated on a 5-point scale and recorded in a quality of life diary for 3 weeks. CD4/8 and NK activity before and after administration of hochuekkito.

#### 7. Main results

General malaise, mood, and appetite showed a tendency for improvement during administration of hochuekkito. There were no significant between-arm differences in CD4/8 or NK activity.

#### 8. Conclusions

Hochuekkito administered during chemotherapy for lung cancer relieves and improves mood and general malaise.

#### 9. From Kampo medicine perspective

The *sho* (証, pattern) concept was not used as a rationale for inclusion or exclusion and was not discussed, although "calculation based on the Kampo score questionnaire revealed 7 patients with *kyosho* (虚証, deficiency pattern) and 2 patients with *chukansho* (中間証, intermediate pattern)."

# 10. Safety assessment in the article

None.

## 11. Abstractor's comments

Despite the lack of statistically significant differences, the authors concluded that hochuekkito may be used to relieve and improve adverse reactions to anticancer drugs (cisplatin  $+\alpha$ ). The bar chart showing the severity of each symptom is meaningless. Although "the data were compared by sign test," the analysis seems to be incorrect.

#### 12. Abstractor and date

Hoshino E, 24 April 2009, 1 June 2010, 31 December 2013.