

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

Ohkawa T, Ebisuno S, Watanabe T, et al. Clinical evaluations of saireito, a herbal drug, for the urological side-effects of cancer chemotherapy. *Biotherapy* 1990;4:1445–60 (in Japanese with English abstract). Ichushi Web ID: 1991149339

**1. Objectives**

To evaluate the efficacy and safety of saireito (柴苓湯) for relieving the adverse urological effects of anticancer drugs.

**2. Design**

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

**3. Setting**

The departments of urology of 12 university hospitals including those of Wakayama Medical University, Nara Medical University, and Osaka University School of Medicine; and the departments of urology of 16 non-university affiliated hospitals, Japan.

**4. Participants**

Two-hundred and seventeen patients with urological cancer treated or to be treated with anticancer drugs.

**5. Intervention**

Arm 1: anticancer drug maintenance therapy + TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d for at least 12 weeks (n=42).

Arm 2: anticancer drug maintenance therapy without administration of Kampo medicine (n=44).

Arm 3: intermittent anticancer therapy + TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d for at least 2 courses (n=38).

Arm 4: intermittent anticancer therapy without administration of Kampo medicine (n=33).

**6. Main outcome measures**

Subjective symptom score (with subscales including general condition, anorexia, general malaise, nausea, vomiting, diarrhea, stomach discomfort, and stomatitis), hematological parameters, and blood biochemistry.

**7. Main results**

Of 217 patients, 60 were excluded from the analyses. There were no significant differences in subjective symptoms between those receiving saireito (arm 1 and arm 3) and those not receiving saireito (arm 2 and arm 4). The decrease in serum creatinine level after 4 weeks was greater in arm 1 than in arm 2, and was significantly greater after 3 courses in arm 3 than in arm 4.

**8. Conclusions**

Saireito is not effective for relieving the adverse effects of anticancer drugs, except for decreasing serum creatinine level.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Adverse reactions occurred in 7 patients (6%): 5 in arm 1 and 2 in arm 3. Treatment was discontinued in 4 of the 5 patients in arm 1 and 1 of the 2 patients in arm 2. Adverse drug reactions included vomiting, diarrhea, anorexia, and stomach pain.

**11. Abstractor's comments**

Although reduction in the adverse effects of anticancer drugs by Kampo formulations has frequently been observed in clinical settings, few full-fledged controlled clinical trials have been conducted. The present study is a valuable multicenter RCT investigating whether saireito relieves the adverse urological effects of anticancer drugs. Although allocation by the envelope method is likely to lead to incomplete randomization, the study found that saireito did not relieve the adverse effects of anticancer drugs. However, saireito did suppress elevation in serum creatinine level suggesting it improves renal function, raising expectations for future studies.

**12. Abstractor and date**

Okabe T, 15 August 2008, 1 June 2010.