

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

Saito Y, Mitsuhashi N, Takahashi I, et al. Effect of TSUMURA Saiboku-to as an agent for healing damage in treatment of radiomucositis due to irradiation of the head and neck area and mediastinum. *Biotherapy* 1992; 6: 1899–906 (in Japanese with English abstract).

1. Objectives

To evaluate the healing effect of TSUMURA Saibokuto (柴朴湯) on mucositis induced by head-and-neck and mediastinal irradiation.

2. Design

Randomized controlled trial (RCT).

3. Setting

Gunma University Hospital and 9 other hospitals (a total of 10 institutions), Japan.

4. Participants

Fifty-four cancer patients were included without regard to their age, sex, primary disease, disease stage, prior treatment, and inpatient or outpatient status. These patients developed symptoms of mucosal irritation in response to head-and-neck or mediastinal irradiation. Exclusion criteria were: serious concomitant diseases of the heart, lung, bone marrow, liver, or kidney; Eastern Cooperative Oncology Group performance status 4; and a determination of ineligibility by the treating physician.

5. Intervention

A telephone system was used for treatment allocation.

Arm 1: TSUMURA Saibokuto (柴朴湯) Extract Granules 2.5 mg t.i.d. was administered orally (before or between meals) for 4 weeks from the onset of some mucosal irritation symptoms after the start of irradiation (12 males and 11 females). The primary diseases included malignant lymphoma, cervical lymph node metastasis, lung cancer, breast cancer, oropharyngeal cancer, and esophageal cancer (in descending order of frequency).

Arm 2: current therapy was continued but TSUMURA Saibokuto (柴朴湯) Extract Granules was not administered. The primary diseases included malignant lymphoma, lung cancer, breast cancer, and cervical lymph node metastasis (in descending order of frequency).

6. Main outcome measures

Severity of subjective symptoms (pharyngolaryngeal pain, foreign-body sensation in the pharyngolarynx, pain on swallowing, difficulty in swallowing, burning sensation, smarting pain) rated on a 4-point scale; objective findings of mucosa (redness, erosion, edema); and global utility (rated on a 3-point scale [marked, moderate, or no response] based on subjective and objective symptoms, laboratory values, and adverse drug reactions).

7. Main results

Three out of 54 enrolled patients in arm 1 were excluded and 20 in arm 1 and 31 in arm 2 were included in the analysis. The comparison of subjective symptom improvements failed to show any efficacy of TSUMURA Saibokuto. Marked and moderate increases in global utility scores were observed in 6 and 6 patients, respectively, in arm 1 and in 0 and 10 patients, respectively, in arm 2; the between-arm difference was significant ($P < 0.01$).

8. Conclusions

TSUMURA Saibokuto may heal mucositis induced by head-and-neck or mediastinal irradiation.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

A mild increase in glutamic-oxaloacetic transaminase (GOT) and glutamic pyruvic trans-aminase (GPT) levels developed in 2 patients in arm 1 who required no specific treatment.

11. Abstractor's comments

Randomization is assumed because treatment allocation used a telephone system (though the details are not clear); so the study was classified as an RCT. There is concern that concurrent use of Predonine (prednisolone) might have influenced outcome in some patients. In this paper, rating criteria for global utility are not clear. More description of these criteria would have aided interpretation of the results. Further studies on this treatment are anticipated.

12. Abstractor and date

Tsuruoka K, 3 April 2008, 1 June 2010, 31 December 2013.