

10. Respiratory Diseases (including Influenza and Rhinitis)**Reference**

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Clinical effect of chai-to-tang (Japanese name: saiboku-to), a Chinese traditional herbal medicine, in patients with bronchial asthma and autonomic nerve dysfunction: A multicenter, randomized, double-blind, placebo-controlled study. *Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)* 2004; 19: 37-41 (in Japanese with English abstract). Ichushi Web ID: 2006203751

1. Objectives

To evaluate the efficacy and safety of saibokuto (柴朴湯) in patients with asthma exacerbations based on anticipatory anxiety.

2. Design

Randomized controlled trial (RCT).

3. Setting

The setting of this study is unstated; the authors of this paper work in clinics, and are specialists in allergic and respiratory medicine, Japan.

4. Participants Shimazaki Y, Mori H, Kurata H, et al. Comparative study of Kampo preparations

Patients with bronchial asthma who fulfill one of the following criteria were included (among 174 subjects participated, data from 172 subjects were analyzed): comprehensive asthma inventory score ≥ 20 , both state trait anxiety inventory (STAI) I and II scores ≥ 41 in men and ≥ 42 in women, or self-rating depression scale (SDS) ≥ 40 .

5. Intervention

Arm 1: Administration of TSUMURA Saibokuto (柴朴湯) Extract Granules 5.0 g/day three times a day before meals for 6 months, n=87.

Arm 2: Administration of lactose 5.0 g/day three times a day before meals for 6 months, n=85.

Each drug was given in indistinguishable capsule.

6. Main outcome measures

Assessment of improvement in objective and subjective symptoms concerning bronchial asthma, various types of mental and psychological tests, assessment of autonomic dysfunction, bronchoalveolar lavage (BAL) fluid, numbers of inflammatory cells in bronchial mucosa biopsy, frequency of asthma exacerbations, levels of hypothalamic, pituitary, and adrenal cortex hormones, assessment of chronic pain, and others.

7. Main results

Autonomic dysfunction, clinical symptoms, and BAL fluid analysis were significantly improved in arm 1 compared to arm 2. In arm 1, the number of subjects with asthma exacerbations decreased from 87 to 14 and the mean duration of asthma exacerbation decreased from 31.5 to 3.1 days, while both indices were increased in arm 2 (descriptions of the results in the text were imprecise).

8. Conclusions

Saibokuto is effective in improving asthma symptoms and psychiatric symptoms in patients with autonomic dysfunction due to asthma.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were no differences between the two arms in the incidences of adverse effects and abnormal laboratory data (no precise description in the paper).

11. Abstractor's comments

As the authors' notes in the Discussion section, this is the first clinical trial in the world to evaluate the effect of saibokuto in patients with bronchial asthma in a randomized, double-blind, controlled design. Following up a number of subjects in detail in multicenter analysis should have required substantial efforts. Declaration of the missing details such as 1) the number of withdrawals during 6 months of observation, 2) the number of subjects who underwent bronchoscopy, and 3) precise data omitted in the Result section, would be effective in making the efficacy of saibokuto widely accepted. Accumulation of such detailed studies may lead to elucidation of the action mechanisms and the efficacy of Kampo medicine, and more similar studies are awaited.

12. Abstractor and date

Goto H, 1 May 2009, 1 June 2010.