

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Clinical effect of a Chinese traditional herbal medicine, chai-po-tang (Japanese name: saiboku-to) compared with clonazepam in patients with bronchial asthmatics and anxiety disorder in multicenter randomized, comparative trial. *Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)* 2002; 17: 20-7 (in Japanese with English abstract). Ichushi Web ID: 2006192005

**1. Objectives**

To assess the efficacy of the anxiolytic-like agent, saibokuto (柴朴湯), in treating bronchial asthma.

**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**

Patients with bronchial asthma who fulfill one of the following criteria were included (n=107): comprehensive asthma inventory score  $\geq 20$ , both state trait anxiety inventory (STAI) I and II scores  $\geq 41$  in men and  $\geq 42$  in women, or self-rating depression scale (SDS)  $\geq 40$ .

**5. Intervention**

Arm 1: administration of TSUMURA Saibokuto (柴朴湯) Extract Granules 2.5 g t.i.d. before meals for 3 years, n=51.

Arm 2: administration of clonazepam 15-30 mg/day (mean 23.9 mg/day) t.i.d. before meals for 3 years, n=56.

**6. Main outcome measures**

Clinical effects, scores various types of mental and psychological tests, airway hyperreactivity, bronchoalveolar lavage (BAL) fluid, improvement in global symptoms (as assessed by a combination of the preceding measures and the development of adverse reactions indicating worsening).

**7. Main results**

Scores on various types of psychological tests, airway hyperreactivity, BAL fluid findings, and global symptoms showed significantly greater improvement in subjects in arm 1 than those in arm 2. The conditions of 68.6% of subjects in arm 1 and 21.3% of subjects in arm 2 were improved or better.

**8. Conclusions**

Saibokuto is significantly more effective than clonazepam in reducing the severity of asthma symptoms in asthma patients with anxiety symptoms.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

In arm 1, there were no adverse reactions or abnormal laboratory findings. In arm 2, there were 13 cases (23.2%) including cases of drowsiness and poor concentration.

**11. Abstractor's comments**

Using a double-blind randomized controlled design, this study provides high-quality evidence that saibokuto is effective for asthma in patients with anxiety symptoms. Withdrawal from the study is not documented in this paper, nor has it been stated whether bronchoscopy was performed in all cases. In the Results section, the authors often use the phrase "results omitted" and do not show the data. Because the results here indicate the efficacy of saibokuto for asthma patients with anxiety symptoms, these data should have been disclosed to further validate its efficacy. However this remains a well-designed study investigating the psychological and organic pathology of asthma and evaluating the long-term efficacy of a Kampo medicine. Further studies including other Kampo formulae are desired.

**12. Abstractor and date**

Goto H, 1 May 2009, 1 June 2010.