

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 ≥ 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 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.