

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

Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Clinical effect of a Kampo medicine, chai-po-tang (Japanese name: saiboku-to) compared with xiao-qing-long tang (Japanese name: shoseiryu-to) in asthmatics with anxiety and depression due to asthmatic attacks. *Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)* 2003; 18: 11-7 (in Japanese with English abstract). Ichushi Web ID: 2006192016

1. Objectives

To compare the efficacy of the anxiolytic-like agent saibokuto (柴朴湯) with that of shoseiryuto (小青竜湯) in patients with 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 allergy and respiratory medicine, Japan.

4. Participants

Patients with bronchial asthma who fulfilled one of the following criteria were included (n=139): 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: TSUMURA Saibokuto (柴朴湯) Extract Granules 5.0 g/day in three divided doses (in capsule form) administered between meals for 24 weeks, n=71.

Arm 2: TSUMURA Shoseiryuto (小青竜湯) Extract Granules 5.0 g/day in three divided doses (in capsule form) administered between meals for 24 weeks, n=68.

6. Main outcome measures

Scores on various types of mental and psychological tests, subjective symptoms, bronchoalveolar lavage (BAL) fluid levels of hormones of the hypothalamo-pituitary-adrenal system, the assessment of suffering from chronic and intractable medical diseases, improvement in global symptoms (rated on a scale from 1 [markedly improved] to 5 [worsened], taking into account disease-related symptoms and the development of adverse reactions).

7. Main results

Various types of psychological tests, subjective symptoms, BAL fluid findings, levels of hormones of the hypothalamo-pituitary-adrenal system, chronic and intractable medical diseases, and global symptom scores showed significantly greater improvement in arm 1 than arm 2. The conditions of 66.2% of subjects in arm 1 and 7.3% in arm 2 were improved or better at the end of the study.

8. Conclusions

Saibokuto is more effective than shoseiryuto in asthma patients with anxiety symptoms.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Although the authors do not offer a detailed description, adverse effects were observed in 2 cases (2.8%) and 5 cases (7.4%) in arm 1 and 2, respectively. Abnormal laboratory findings were noted in 2 cases (2.8%) in arm 1 and 6 cases (8.8%) in arm 2.

11. Abstractor's comments

Using a double-blind randomized controlled design, this study provides high-quality evidence that saibokuto and shoseiryuto are effective for asthma in patients with anxiety symptoms. As the authors refer to development of adverse reactions, the number of withdrawals and the reasons for withdrawal should have been included to make this report even better. Accumulation of the detailed comparative information about these two Kampo drugs will clarify understanding of how both drugs work.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010.