

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

Urata Y, Yoshida S, Irie Y, et al. Treatment of asthma patients with herbal medicine TJ-96: a randomized controlled trial. *Respiratory Medicine* 2002; 96: 469-74. CENTRAL ID: CN-00390241, Pubmed ID: 12117049

1. Objectives

To investigate the clinical effect of saibokuto (柴朴湯) for the treatment of atopic asthma.

2. Design

Randomized controlled trial (cross over) (RCT-cross over).

3. Setting

One university hospital and one hospital, Japan.

4. Participants

Adult patients with atopic asthma, n=33.

5. Intervention

Since allocation of patients to these treatment arms is not mentioned, the treatment arms are described in terms of treatment regimen.

Cross-over design (administration of saibokuto (柴朴湯) or placebo [2.5 g, t.i.d.] for 4 weeks, and then, after a washout period of at least 4 weeks, patients crossed over to receive the alternative treatment), n=33.

Arm 1: TSUMURA Saibokuto (柴朴湯) Extract Granules (TJ-96).

Arm 2: placebo.

6. Main outcome measures

Clinical symptoms, respiratory function test, methacholine provocation testing, eosinophil counts in blood and sputum, and eosinophilic cationic protein (ECP) in blood and sputum.

7. Main results

Symptom score (which employed similar severity classification according to Guidelines for Asthma Prevention and Management 2004 [JGL 2004]) before treatment was 1.65 ± 0.38 in arm 1 and 1.66 ± 0.43 in arm 2. After treatment, it was significantly decreased in arm 1 (0.73 ± 0.25 in arm 1 and 1.63 ± 0.39 in arm 2, $P=0.001$). Forced expiratory volume in 1 second ($FEV_{1.0}$) improved slightly but not significantly in arm 1. Response to provocation challenge with methacholine was significantly better in arm 1. Significant decreases in eosinophil counts and ECP in blood and sputum but not neutrophil counts were observed in arm 1.

8. Conclusions

Saibokuto improves clinical symptoms in patients with atopic asthma. Although $FEV_{1.0}$ and FVC were unaffected, saibokuto was able to attenuate eosinophilic inflammation.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

This is a high-quality trial, a double-blind RCT with a placebo control group for evaluation of saibokuto (柴朴湯) extract granules as treatment for asthma. Although there was no between-group difference in pulmonary function ($FEV_{1.0}$ and FVC), there was a significant between-group difference in subjective symptoms. The respiratory function data obtained in this study should be useful for sample selection in future RCTs.

12. Abstractor and date

Fujisawa M, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.