

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

Egashira Y, Nagano H, et al. Results of a comparative clinical study of the effect of "TSUMURA Saiboku-to" (TJ-96) against steroid dependent bronchial asthma in 2 groups, a Saiboku-to administration group and a non-administration group, divided by the envelope method. *Kampo to Meneki-Arerugi (Kampo and Immuno-allergy)* 1990; 4: 128-44 (in Japanese with English abstract).

Egashira Y, Nagano H. A multicenter clinical trial of TJ-96 in patients with steroid-dependent bronchial asthma. A comparison of groups allocated by the envelope method. *Annals of the New York Academy of Science* 1993; 685: 580-3. CENTRAL ID: CN-00095466, Pubmed ID: 8363267

1. Objectives

To evaluate the effectiveness, safety, and usefulness of saibokuto (柴朴湯) against steroid-dependent bronchial asthma.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Twenty university hospitals and 31 hospitals, Japan.

4. Participants

Patients with bronchial asthma treated with steroids (n=112).

5. Intervention

Arm 1: administration of TSUMURA Saibokuto (柴朴湯) Extract Granules 2.5 g t.i.d. for 12 weeks (n=64).

(The patients receiving more than 5 mg/day of prednisolone (-equivalent dose of steroids) [n=37]; patients with asthma for more than 5 years [n=48])

Arm 2: no administration (n=48).

(The patients receiving more than 5 mg/day of prednisolone (-equivalent dose of steroids) [n=25]; patients with asthma for more than 5 years [n=41])

6. Main outcome measures

Asthma score = attack score (severity) + treatment score (level of the concomitant drugs). Scores and the number of subjects who succeeded in decreasing steroid doses.

7. Main results

A larger percentage of patients in arm 2 had moderate or greater improvement (32.8% vs. 10.4% in arm 1) and slight or greater improvement (60.9% vs. 18.8% in arm 1; $P < 0.001$). A larger percentage of patients in arm 2 had reduction in steroid dose of 50% or more (17.2% vs. 6.3% in arm 1; $P < 0.01$), which showed the significant steroid sparing effect of saibokuto.

8. Conclusions

Saibokuto improves the clinical symptoms of asthma and leads to a reduction in the dosage of concomitantly administered steroids.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Stomach pain and stomach discomfort were observed in 1% of the saibokuto group.

11. Abstractor's comments

The article by Egashira et al (1993) was based on the original article by Egashira et al (1990), and it includes detailed analysis of individual cases. The RCT report published in *Ann. N.Y. Acad. Sci.* was also cited in "Huntley A, Ernst E. Herbal medicines for asthma: a systematic review, *Thorax*, 2000; 55:925-929." Future promise lies in an RCT incorporating Kampo patterns, after clinical trial registration.

12. Abstractor and date

Fujisawa M, 31 March 2008, 1 June 2010, 31 December 2013.