

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

Miyamoto T, Inoue H, Kitamura S, et al. Effect of TSUMURA Sho-seiryu-to (TJ-19) on bronchitis in a double-blind placebo-controlled study. *Rinsho Iyaku (Journal of Clinical Therapeutics & Medicine)* 2001; 17: 1189-214 (in Japanese with English abstract). Ichushi Web ID: 2002029631, [MOL](#), [MOL-Lib](#)

Miyamoto T. Clinical effectiveness of Shosei-ryuto in bronchitis. *Pharma Medica* 2007; 25: 23-5 (in Japanese). Ichushi Web ID: 2008035989 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the efficacy and safety of shoseiryuto (小青竜湯) in the treatment of bronchitis.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

Seventeen university hospitals, forty-two hospitals, and three clinics, Japan.
From December 1994 until March 1999.

4. Participants

Patients aged 16 to <65 years with mild to moderate bronchitis, and evaluable symptoms (any of watery sputum, rales/rhonchi, and cough).

5. Intervention

The concomitant use of other drugs was prohibited with the exception of dimemorfan phosphate (Astomin) after day 4.

Arm 1: TSUMURA Shoseiryuto (小青竜湯) Extract Granules (TJ-19) 3.0 g t.i.d. for 7 days, n=101.

Arm 2: placebo 3.0 g t.i.d. for 7 days, n=91.

6. Main outcome measures

Global improvement (rate), improvement of bronchitis symptoms (such as cough and sputum), and safety.

7. Main results

At the end of treatment, there was a trend toward higher percentage of patients with moderate-to-marked global improvement in arm 1, compared with arm 2 (57.4% in arm 1 vs 42.9% in arm 2; $P=0.06$). No significant difference was observed at day 3 or 4. As for improvement of each symptom, ease of raising sputum, properties of sputum (purulent, viscous, etc.), and disturbance in activities of daily living, was significantly better in arm 1 at days 3-4. At the end of treatment, there was significant improvement in frequency of coughing, intensity of coughing, ease of raising sputum, and activities of daily living, and a tendency toward improvement in sneezing and nasal obstruction in arm 1.

8. Conclusions

Shoseiryuto is effective for bronchitis with mild symptoms.

9. From Kampo medicine perspective

Inclusion criteria of patients with watery sputum, rales/rhonchi, and/or cough were chosen to adopt the “*sho* (証, pattern)” for shoseiryuto in Kampo medicine. Further subgroup analyses in patients without physical frailty and those with cough and watery sputum showed a significantly higher rate of global improvement in arm 1 than arm 2.

10. Safety assessment in the article

The incidence of adverse effects was 6.7% (7 cases) in arm 1 and 9.9% (9 cases) in arm 2, with no significant difference. No serious adverse effects were found.

11. Abstractor's comments

This is a full-scale DB-RCT that addresses Kampo patterns. The authors carry out sub-group analyses based on patterns, in accordance with the clinical guidelines for re-evaluation of Kampo formulations, as indicated in Harumi K, et al.: 1991 Report of the Kampo extract formulation clinical evaluation methods research group, *Japanese Journal of Clinical Pharmacology and Therapeutics*, 1991; 22: 781-91 (in Japanese). The study finds that improvement was greater in the group with watery sputum and cough. These guidelines for the clinical evaluation of Kampo formulations ought to be more widely known and used.

12. Abstractor and date

Fujisawa M, 15 June 2007, 22 February 2009, 1 June 2010, 31 December 2013.