Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Mori H. Comparative study of Kampo preparations sho-seiryu-to and dai-seiryu-to for nasal allergy and allergic conjunctivitis. *Therapeutic Research* 1998; 19: 3299-307 (in Japanese with English abstract). MOL, MOL-Lib

1. Objectives

To evaluate the efficacy of shoseiryuto (小青竜湯) and daiseiryuto (大青竜湯) (keishito plus makyokansekito) (桂枝湯合麻杏甘石湯) for spring allergic rhinitis (pollinosis).

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One clinic, Japan.

4. Participants

Fifty-six patients who were first diagnosed with pollinosis from January 26, 1998 to April 9, 1998. *Kyo-sho* (虚証, deficiency pattern) patients were excluded.

5. Intervention

Arm 1: Kotaro Shoseiryuto (小青竜湯) Extract Fine Granules 2.5 g t.i.d. (28 patients enrolled, 15 patients analyzed).

Arm 2: Daiseiryuto (大青竜湯) (Kotaro Keishito [桂枝湯] Extract Fine Granules 5 g + Kotaro Makyokansekito [麻杏甘石湯] Extract Fine Granules 9 g) 14.0 g/day in three divided doses (28 patients enrolled, 24 patients analyzed).

Group assignment in the order of receipt; concomitant use of Intal Nasal Drops/Eye Drops (sodium cromoglycate) for severe symptoms.

6. Main outcome measures

Measures of severity of sneezing, runny nose, nasal congestion, periocular itching, lacrimation, eye discharge, and eye pain.

7. Main results

There was no significant between-arm improvement in symptoms. Overall improvement (in severity of nasal symptoms) was mild or better in 46.7% and 87.5% of patients in Arms 1 and 2, respectively, and significantly different between arms.

8. Conclusions

Shoseiryuto and daiseiryuto have similar efficacy for individual symptoms; daiseiryuto has significantly greater clinical efficacy than shoseiryuto for overall symptoms.

9. From Kampo medicine perspective

Since shoseiryuto is used in *chukan-sho* (中間証, intermediate pattern) to *jitsu-sho* (実証, excess pattern)patients, physically weak patients were excluded. Because "Mori H, Shimazaki Y, Kurata H, et al. Comparative study of Kampo preparations Sho-Seiryu-To and Eppika-Jutsu-To for nasal allergy and allergic conjunctivitis. *Therapeutic Research* 1997; 18: 3093-9 (in Japanese with English abstract)" showed that eppikajutsuto was effective for pollinosis, daiseiryuto (containing mao [麻黄, ephedra herb]and sekko [石膏, gypsum], constituent crude drugs of eppikajutsuto) was used in this controlled trial.

10. Safety assessment in the article

One patient treated with daiseiryuto experienced hand, foot, and eyelid edema and body weight gain, which were later found to be associated with pseudoaldosteronism.

11. Abstractor's comments

Dr. Mori's articles on pollinosis have focused on shoseiryuto. Refer to "Baba S, Takasaka T, Inamura N et al. Efficacy of shoseiryuto for perennial nasal allergy - double-blind controlled study - *Jibiinkoka Rinsho* (*Practica otologica*) 1995; 88: 389-405".

12. Abstractor and date

Fujisawa M, 13 October 2008, 6 January 2010, 1 June 2010.