10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Yoshimoto T, Mori H, Kurata H, et al. Comparative study of Kampo preparations sho-sei-ryu-to and maoh-bushi-saisin-to for nasal allergy and allergic conjunctivitis in spring. *Therapeutic Research* 2002; 23: 2253-9 (in Japanese with English abstract). Ichushi Web ID: 2003161479 MOL, MOL-Lib

1. Objectives

To compare the effects of shoseiryuto (小青竜湯) and maobushisaishinto (麻黄附子細辛湯) in treating springtime nasal allergy and allergic conjunctivitis.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Five clinics of internal medicine, Japan.

4. Participants

Of the patients who visited the above-mentioned clinics for the first time with springtime nasal allergy and allergic conjunctivitis (allergic rhinitis), 66 having previously diagnosed pollen hypersensitivity/pollinosis or newly diagnosed rhinitis with increased eosinophils in nasal discharge and elevated IgE level were enrolled. Exclusion criteria were: "*kyo-sho* (虚証, deficiency pattern)," sinusitis, nose disorders such as nasal septal deviation, conjunctivitis other than allergic conjunctivitis, pregnancy, and refusal to take Kampo medicines.

5. Intervention

Arm 1: TSUMURA Shoseiryuto (小青竜湯) Extract Granules (TJ-019) 3.0 g t.i.d., n=34.
Arm 2: TSUMURA Maobushisaishinto (麻黄附子細辛湯) Extract Granules (TJ-127) 2.5 g t.i.d., n=32.
Concomitant drug use was prohibited, with the exception of Intal eye drops or nasal spray for severe and intolerable symptoms.

6. Main outcome measures

Symptom improvement: Each of nose and eye symptoms after 2-week administration was rated on a 5-point scale (markedly improved, moderately improved, slightly improved, unchanged, and aggravated).
Global improvement: The severity of illness (nose and eye symptoms) after 2-week administration, compared with that before treatment, was rated on a 5-point scale (as maobushisaishinto acts rapidly, change in the symptoms was recorded beginning one week after the initiation of treatment.)
Overall safety: Adverse drug reactions after 2-week administration were evaluated on a 5-point scale.
Usefulness: The global improvement combined with overall safety was assessed on a 5-point scale (very useful, useful, slightly useful, indiscernible, and useless).

7. Main results

Slight-to-marked (or moderate-to-marked) improvement was seen in each of the following symptoms: sneezing (41.2% and 59.4% in arms 1 and 2, respectively), rhinorrhea (47.1% and 53.1%), nasal obstruction (58.8% and 37.5%), periocular pruritus (35.3% and 45.2%), lacrimation (23.5% and 19.4%), and ocular discharge (11.8% and 9.7%). The chi-square test and Mann-Whitney *U* test revealed no significant differences in improvement of any symptoms between the two arms. Also, there was no significant difference between the arms in global improvement (slight-to-marked global improvement in 67.6% and 71.9% for arms 1 and 2, respectively, and moderate-to-marked global improvement, 52.9% and 53.1%). As for usefulness, interventions were assessed to be "useful or very useful" in 50% for arm 1 and 50% for arm 2, with no significant between-arm difference.

8. Conclusions

Maobushisaishinto is suggested to be as effective as shoseiryuto in treating springtime nasal allergy and allergic conjunctivitis.

9. From Kampo medicine perspective

Maobushisaishinto is more suitable than shoseiryuto for treating subjects with "*kyo-sho*," who are frail or elderly.

10. Safety assessment in the article

No adverse drug reactions were observed in either arm.

11. Abstractor's comments

This study followed a RCT of shoseiryuto for nasal allergy and allergic conjunctivitis in spring (*Jibiinkoka Rinsho* [*Practica otologica*] 1995; 88: 389-405 [in Japanese]), and uses the same outcome measures. However, patients were allocated sequentially and not properly randomized, making this study a clinical controlled trial (CCT: quasi-RCT). Results with no significant differences in this study provide a new therapeutic option for springtime nasal allergy and allergic conjunctivitis, and can be regarded as clinically meaningful.

12. Abstractor and date

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010.