Evidence Reports of Kampo Treatment

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, Kurata H, Shimazaki Y, et al. Comparative study of Kampo preparations sho-sei-ryu-to and kei-ma-kakuhan-to for nasal allergy and allergic conjunctivitis in spring. *Therapeutic Research* 1999; 20: 2941-7 (in Japanese with English abstract). MOL, MOL-Lib

1. Objectives

To compare the efficacy of shoseiryuto (小青竜湯), and keimakakuhanto (桂麻各半湯) in treating springtime nasal allergy and allergic conjunctivitis.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

From 25 January 1999 until 10 April 1999.

One hospital and three clinics of internal medicine, Japan.

4. Participants

Eighty eight patients with springtime nasal allergy and allergic conjunctivitis. Of these patients, 65 were included for analysis.

5. Intervention

Arm 1: TSUMURA Shoseiryuto (小青竜湯) Extract Granules (TJ-19) 3.0 g, t.i.d. for 2 weeks, n=32.

Arm 2: keimakakuhanto (桂麻各半湯) 8.0 g/day in three divided doses (4.0 g of TSUMURA Keishito (桂枝湯) Extract Granules [TJ-45] + 4.0 g of TSUMURA Maoto (麻黄湯) Extract Granules [TJ-27]) for 2 weeks, n=33.

6. Main outcome measures

Improvement in each symptom and global improvement.

7. Main results

Efficacy (percent improvement in arm 1 and arm 2, respectively) was observed against sneezing (68.8% and 66.7%), rhinorrhea (56.3% and 63.6%), nasal sinus obstruction (40.6% and 30.3%), and periocular pruritus (46.9% and 54.5%); there was no significant difference in between-arm improvements.

As for global improvement, 62.5% and 60.6% of patients in arm 1 and arm 2, respectively, were rated "moderately-to-markedly improved," demonstrating no significant between-arm difference in efficacy.

8. Conclusions

Keimakakuhanto is as effective as shoseiryuto in treating springtime nasal allergy and allergic conjunctivitis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

In the shoseiryuto arm, two subjects reported dry mouth, one reported gastric distension, and one reported stomach discomfort leading to discontinued administration; and in the keimakakuhanto arm, one reported dry mouth and one discontinued administration because of nausea.

11. Abstractor's comments

As of 1999, no definite evidenced-based medicine (EBM) approach had been used to study the efficacy of Kampo formulations in treating springtime nasal allergy and allergic conjunctivitis. This paper presents a comparative study of the efficacies of two Kampo medicines, and further placebo-controlled analysis is awaited.

12. Abstractor and date

Fujisawa M, 15 June 2007, 1 April 2008, 1 June 2010.