10. Respiratory Diseases (including Influenza and Rhinitis)

References

Ohya Y. Kampo treatment for allergic diseases -from the viewpoint of a general hospital-. *Progress in Medicine* 1988; 8: 604–12 (in Japanese).

Ohya Y. Efficacy of preseasonal administration of shoseiryuto for cedar pollen allergy*. Kampo Shinryo 1991; 10: 42–8 (in Japanese).

1. Objectives

To evaluate the preventive effect and safety of preseasonal administration of syoseiryuto (小青竜湯) against cedar pollen allergy.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital (a department of otolaryngology), Japan.

4. Participants

Patients with cedar pollen allergy of mild or less severity (n=43).

5. Intervention

Arm 1: TSUMURA Shoseiryuto (小青竜湯) Extract Granules (TJ-19) 3 mg t.i.d. for 57 days (n=23).
Arm 2: ketotifen 1 g b.i.d. for 57 days (n=20).
Treatment period was from 7 February to 4 April 1987.

6. Main outcome measures

Change in subjective nasal symptoms was graded on a scale of 1–4 before and during the pollen dispersal period.

7. Main results

The data of 29 patients who completed nasal allergy diaries (15 in arm 1 and 14 in arm 2) were analyzed. There were no significant between-arm differences in moderate or better improvement effects on the following symptoms: sneezing (66.7% in arm 1, 64.3% in arm 2), nasal discharge (60% in arm 1, 57.1% in arm 2), nasal obstruction (86.7% in arm 1, 85.7% in arm 2), and overall nasal symptoms (66.7% in arm 1, 64.3% in arm 2).

8. Conclusions

Preventive effects of shoseiryuto and ketotifen on cedar pollen allergy are equivalent.

9. From Kampo medicine perspective

Among the 15 patients in the shoseiryuto arm, 1 patient had *jitsu-sho* (実証, excess pattern) and 14 patients had *chukan-sho* (中間証, intermediate pattern).

10. Safety assessment in the article

Mild diarrhea was observed in 1 patient in arm 1.

11. Abstractor's comments

This randomized controlled trial demonstrated that the clinical effectiveness of shoseiryuto for preventing mild cedar pollen allergy was equivalent to that of the oral anti-allergy drug ketotifen. The flaw in this study is that the endpoint is not objective. Change in the subjective nasal symptoms is judged from patients' nasal allergy diaries. Also the patients enrolled in this study have mild or less severity disease and therefore the results of this study should be evaluated with caution. Shoseiryuto is expected to prevent cedar pollen allergy in patients with the appropriate *sho*. However, further clinical trials considering this point are awaited.

12. Abstractor and date

Okabe T, 18 August 2008, 1 June 2010, 31 December 2013.