10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

1. **Objectives**
To determine the effectiveness of Kampo medicines for chronic rhinitis and sinusitis.

2. **Design**
Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. **Setting**
One university and 5 hospitals, Japan.

4. **Participants**
Six patients with non-allergic chronic rhinitis and 61 with chronic sinusitis who first visited the participating institutions between November 1989 and June 1990.

5. **Intervention**
Arm 1: oral administration of TSUMURA Shin’iseihaito (辛夷清肺湯) Extract Granules 2.5 g t.i.d. before meals for 4-8 weeks (n=39).
Arm 2: oral treatment with TSUMURA Shigyakusan (四逆散) Extract Granules 2.5 g t.i.d. before meals for 4-8 weeks (n=28).

6. **Main outcome measures**
Severity of subjective symptoms: rhinorrhea, ease of nose blowing, postnasal drip, nasal obstruction, heaviness of head (headache), and olfactory disturbance.
Objective findings: redness and edema of the nasal mucosa, characteristics of nasal discharge.
Examinations: neutrophil count in nasal discharge, rhinomanometry.

7. **Main results**
Improvement in subjective symptoms was at least mild in 76.3% and 59.3% of patients in arms 1 and 2, respectively; the between-arm difference was not significant. Improvements in objective findings were not significantly different between arm 1 (60.5%) and arm 2 (70.4%). There were no significant between-arm differences in neutrophil count, nasal discharge, and rhinomanometric results.

8. **Conclusions**
The preceding paper was Ikeda K, Takasaka T, Kusakari J, et al. Outcome of treatment with Leftose (lysozyme hydrochloride) for chronic sinusitis – a comparison of clinical efficacy in adults versus children -. *Jibiinkoka Rinsho (Practica otologica)* 1984;77:1863–69. The present study revealed that Kampo medicines had efficacy comparable with that of Leftose (i.e., mild or greater improvement in 63% of patients with chronic sinusitis).

9. **From Kampo medicine perspective**
None.

10. **Safety assessment in the article**
One shin’iseihaito-treated patient had chest distress, which was considered unlikely to be related to the drug.

11. **Abstractor’s comments**
In the treatment of chronic sinusitis, long-term low-dose administration of 14-membered ring macrolide antibiotics became available around 1990 and now these antibiotics are used as standard conservative therapy. Anti-inflammatory enzymes, including Leftose, were commonly used before 1990 and otology physicians reported reasonably adequate efficacy of these drugs. Now they are combined with these antibiotics to relieve symptoms.

12. **Abstractor and date**
Fujisawa M, 1 June 2009, 1 June 2010.