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

Nishizawa Y, Nishizawa Y, Goto HG et al. Chronic pain in intractable and chronic internal diseases<sup>\*</sup>. *Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)*, 2002; 21: 67-77 (in Japanese with English abstract). Ichushi Web ID: 2003126703 MOL, MOL-Lib

#### 1. Objectives

To investigate the effect of saibokuto (柴朴湯) inhalation therapy in improving quality of life (QOL) in patients with aspirin-intolerant asthma.

#### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

One hospital and two clinics, Japan.

## 4. Participants

Patients with aspirin-intolerant asthma, n=214.

#### 5. Intervention

The study duration was 3 years. For saibokuto (柴朴湯) inhalation, 500 µg of saibokuto was packed into capsules comparable to those used for sodium cromoglycate (DSCG) inhalation. Arm 1: saibokuto (柴朴湯) (the manufacturer not identified), 500 µg q.i.d. inhalation, n=105. Arm 2: DSCG 20 mg q.i.d. inhalation, n=109.

#### 6. Main outcome measures

Subjective symptoms, various tests, chronic pain, and QOL were assessed using a visual analog "total disease-related symptoms" scale developed by the authors, and face rating scores.

#### 7. Main results

Saibokuto inhalation improved various endpoints.

#### 8. Conclusions

Symptom-related QOL of patients with exacerbated aspirin-intolerant asthma is improved.

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

#### **10.** Safety assessment in the article

The incidence of adverse effects was higher in arm 1, however, there was no significant difference in the number of cases. These results were omitted from the original article.

#### **11.** Abstractor's comments

This RCT resembles two other RCTs of saibokuto inhalation therapy, "Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Suppressive Effect of Japanese Herbal Medicine, Saiboku-to (Cai-Pu-Tang) on Brochospasms in Aspirin-induced Bronchial Asthmatic Patients. A Randomized, Double-blind Test. *Jibi-inkoka Tenbo (Oto-Rhino-Laryngology Tokyo)* 2001; 44: 5-13 (in Japanese with English abstract)" and "Nishizawa Y, Nishizawa Y, Yoshioka F, et al. Suppressive effect of Kampo medicine, Cai-pu-tang (Japanese name: Saiboku-to, TJ-96) on brochospasms in aspirin-induced bronchial asthmatic patients and decrease of chronic pain. Especially psychological pain. *Itami to Kampo (Pain and Kampo Medicine)* 2001; 11: 14-21 (in Japanese with English abstract)". The only difference between these studies is the method of administering the inhalant: inhalation of saibokuto dissolved in distilled water or saline, or as a powder using a spinhaler as mentioned in this paper. Inhalation of powder should further improve QOL because powder increases accessibility. Common to these three papers is their complicated format, poorly-described rationale, and omission of results, which makes understanding the contents more difficult.

#### 12. Abstractor and date

Fujisawa M, 22 February 2009, 1 June 2010.