10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

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). Ichushi Web ID: 2002261501

1. Objectives

To evaluate the efficacy of long-term inhaled saibokuto（柴朴湯）in alleviating psychological suffering.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

One hospital and three clinics, Japan.

4. Participants

Thirty-two patients with aspirin-induced asthma.

5. Intervention

Since allocation to these treatment arms is not described, the treatment arms are described in terms of treatment regimen.

Arm 1: Saibokuto (柴朴湯) inhalation group (TSUMURA Saibokuto (柴朴湯) Extract Granules 1 mg dissolved in 1 ml of distilled water for injection, then sonicated for 90 minutes before Millipore filtration. Concentration adjusted to 100 μg/ml and 5 ml inhaled b.i.d.)

Arm 2: Placebo inhalation group (distilled water for injection inhaled b.i.d.)

Inhalation treatment lasts 6 months and is followed by washout for 4 weeks and inhalation treatment using the other liquid for 4 weeks (n=32).

6. Main outcome measures

Chronic pain (CP): Overall quality of life (QOL), visual analogue scale for pain (VAS-P), face rating score, QOL scores (quality of well-being scale [QWB] score, Modified Health Assessment Questionnaire [MHAQ], face scale)

7. Main results

In the trial of long-term inhalation, significant improvements were observed in each QOL domain and also in global QOL scores (this global QOL assessment method was developed by the authors using a visual analog scale [VAS] to assess physical [QOL-P], mental/psychological [QOL-M], social activity [QOL-S], medical economics [QOL-E], therapeutic drug [QOL-D], and individual QOL [QOL-I] incorporated items measuring the perspectives of individuals [including his/her perspectives on philosophy, thoughts, ethics, generation, policy, religion, and so on], as well as face scale and modified health assessment questionnaires)..

8. Conclusions

Inhaled saibokuto therapy improves QOL and respiratory function.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Dysguesia (or altered sensation of taste) was observed in 5 cases (15.6%) in arm 1 and in 2 cases (6.3%) in arm 2. Cacosmia (or imagining of unpleasant odors) was observed in 7 cases (21.9%) in arm 1 and in 4 cases (12.5%) in arm 2. None of these adverse effects caused withdrawal from the study.

11. Abstractor's comments

The paper also mentions a comparative study of TJ-96 immediately after inhalation; however, it did not clearly describe the sample population, method of allocation, and results. Thus, the study was not reported as an RCT. Furthermore, saibokuto (柴朴湯) inhalation liquid is not simply extract granules dissolved in distilled water for injection: it is a special medicine with an altered formulation, made using an original process.

12. Abstractor and date

Fujisawa M, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.