

10. Respiratory Diseases (including Influenza and Rhinitis)**Reference**

Nishizawa Y, Nishizawa Y, Nagano F, et al. Sparing effect of saibokuto inhalation on inhaled beclomethasone dipropionate to halved of reduction of inhaled beclomethasone dipropionate-dose: well-controlled comparative study of saiboku-to-inhalation and sodium cromoglycate-inhalation. *Jibi-inkoka Tenbo (Oto-rhino-laryngology Tokyo)* 2002; 45: 8-15 (in Japanese with English abstract).
CENTRAL ID: CN-00403706, Ichushi Web ID: 2003036732

1. Objectives

To assess the efficacy and safety of inhaled saibokuto (柴朴湯) while reducing the amount of inhaled beclomethasone during the course of treatment for bronchial asthma.

2. Design

Randomized controlled trial (RCT).

3. Setting

Several clinics and others, Osaka prefecture, Japan.

4. Participants

Patients with stable bronchial asthma whose peak expiratory flow rate was maintained at more than 70% of normal for 6 months by the use of inhaled beclomethasone (800 µg/day), n=94.

5. Intervention

Amount of inhaled beclomethasone was reduced from 800 µg/day to 400 µg/day at 4 weeks before the intervention.

Arm 1: inhaled saibokuto (柴朴湯), 500 µg q.i.d., n=49.

Arm 2: inhaled cromoglycate, 20 mg q.i.d., n=45.

Duration of the study was 12 months.

6. Main outcome measures

1) Intensity of subjective symptoms (visual analogue scale), 2) peak expiratory flow (respiratory function test), 3) frequency of the use of β_2 -agonist, 4) cytokine levels in bronchial lavage fluid, 5) nitric oxide (NO) concentrations in expired air, and so on.

7. Main results

In arm 1, subjective symptoms and respiratory function were significantly improved, and compared to arm 2, patients in arm 1 had significantly reduced frequency of β_2 -agonist use, NO concentration in expired air, and cytokine levels in bronchial lavage fluid. Less than 10% decrease in the peak expiratory flow rate occurred in 67.3% of arm 1 and 13.3% of arm 2.

8. Conclusions

Inhaled saibokuto therapy is suggested to maintain the efficacy of inhaled beclomethasone as treatment for bronchial asthma despite dosage reduction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse effects occurred in 11 cases (22.4%) in arm 1, and in 8 cases (17.8%) in arm 2.

11. Abstractor's comments

Although they mention a multicenter study, the authors cite only one research institute, and do not specify the facilities where the clinical trials were actually conducted. The number of withdrawals during the 1-year follow-up and the percentage of the 94 enrolled patients who were actually included for analysis were not stated. Perhaps no one withdrew during the 1 year of treatment. Inhaled saibokuto therapy is assumed to be efficient compared to inhaled cromoglycate. All participants in this study should be considered adult patients with mild asthma. In terms of Kampo medicine, bronchial asthma presents a variety of “*sho* (証, pattern).” Previous studies demonstrated that oral administration of saibokuto shows only limited clinical efficiency for those who do not have “*sho*” for saibokuto.

12. Abstractor and date

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010.