10. Respiratory Diseases (including Influenza and Rhinitis)

References

1. Objectives
   To evaluate the effectiveness, safety, and usefulness of saibokuto (柴朴湯) against steroid-dependent bronchial asthma.

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

3. Setting
   Twenty university hospitals and 31 hospitals, Japan.

4. Participants
   Patients with bronchial asthma treated with steroids (n=112).

5. Intervention
   Arm 1: administration of TSUMURA Saiboku (柴朴湯) Extract Granules 2.5 g t.i.d. for 12 weeks (n=64).
   (The patients receiving more than 5 mg/day of prednisolone (-equivalent dose of steroids) [n=37]; patients with asthma for more than 5 years [n=48])
   Arm 2: no administration (n=48).
   (The patients receiving more than 5 mg/day of prednisolone (-equivalent dose of steroids) [n=25]; patients with asthma for more than 5 years [n=41])

6. Main outcome measures
   Asthma score = attack score (severity) + treatment score (level of the concomitant drugs). Scores and the number of subjects who succeeded in decreasing steroid doses.

7. Main results
   A larger percentage of patients in arm 2 had moderate or greater improvement (32.8% vs. 10.4% in arm 1) and slight or greater improvement (60.9% vs. 18.8% in arm 1; P<0.01). A larger percentage of patients in arm 2 had reduction in steroid dose of 50% or more (17.2% vs. 6.3% in arm 1; P<0.01), which showed the significant steroid sparing effect of saibokuto.

8. Conclusions
   Saibokuto improves the clinical symptoms of asthma and leads to a reduction in the dosage of concomitantly administered steroids.

9. From Kampo medicine perspective
   None.

10. Safety assessment in the article
    Stomach pain and stomach discomfort were observed in 1% of the saibokuto group.

11. Abstractor’s comments

12. Abstractor and date