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

Sasaki H, Sato K, Sasaki M, et al. Usefulness of Bakumondo-to in senile, chronic respiratory disease patients having difficulty in expectoration: comparison with bromhexine hydrochloride preparations. *Kampo to Meneki-Arerugi (Kampo and Immuno-allergy)* 1993; 7: 139–45 (in Japanese with English abstract).

1. Objectives

To evaluate the effectiveness of bakumondoto (麦門冬湯) in loosening phlegm in comparison with a bromhexine hydrochloride preparation.

2. Design

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

3. Setting

One university hospital and six hospitals, Japan.

4. Participants

Patients aged 65 years or older with difficulty in expectoration who have chronic respiratory diseases such as chronic bronchitis, emphysema, pulmonary fibrosis, bronchial asthma, bronchiectasis, old tuberculosis, and pneumoconiosis (n=19).

5. Intervention

Arm 1: dministration of TSUMURA Bakumondoto (麦門冬湯) Extract Granules 2.5 g t.i.d. for 4 weeks (n=10).

Arm 2: administration of bromhexine hydrochloride 4 mg t.i.d. for 4 weeks (n=9).a

6. Main outcome measures

Subjective symptoms: frequency of cough, intensity of cough, stridor, volume of sputum, retention of sputum, and clearance of sputum.

7. Main results

No improvement in the frequency of cough, intensity of cough, stridor, and volume of sputum was observed in either arm. In contrast, there was significant improvement in retention of sputum after 2 weeks in arm 1, and a tendency toward improvement in arm 2. Clearance of sputum was also significantly improved after 2 and 4 weeks of treatment in arm 1, but less improved in arm 2. The percentage of patients with more than moderate general improvement was 60.0% in arm 1 and 11.1% in arm 2, but the between-arm difference was not statistically significant.

8. Conclusions

Bakumondoto can be used in the aged without adverse effects, and has significant efficacy in loosening phlegm in patients with chronic lung disease.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

No safety issues were identified.

11. Abstractor's comments

As mentioned in the introduction of this article, "the significance of expectorants is not always recognized. For instance, there is no definite answer to the question whether we should increase or suppress the volume of sputum to improve difficulty in expectoration. In fact, expectorants are not sold in the United States." This is what I realize at the moment. Moreover, bakumondoto is an expectorant I actually prescribe.

12. Abstractor and date

Fujisawa M, 13 October 2008, 1 June 2010, 31 December 2013.