Respiratory Diseases (including Influenza and Rhinitis)

Reference

Watanabe N, Miyazawa T. Comparative study of the effect of bakumondoto and tipepidine hebinzate on cough in patients with mycoplasmal bronchitis. *Kampo to Meneki-Arerugi* (*Kampo and Immuno-Allergy*) 2007; 21: 31-6 (in Japanese).

1. Objectives

To compare the efficacy of bakumondoto (麦門冬湯) and tipepidine hibenzate as antitussive agents in patients with mycoplasmal bronchitis.

2. Design

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

3. Setting

An internal medicine department in a hospital (the authors belong to the Division of Respiratory and Infectious Diseases, Department of Internal Medicine, St. Marianna University School of Medicine).

4. Participants

Female patients with mycoplasmal bronchitis who exhibited no signs of pneumonia on chest radiographs, n=14.

5. Intervention

Arm 1: administration of azithromycin 500 mg for 3 days, Tsumura Bakumondoto (麦門冬湯) Extract Granules (TJ-29) 3.0 g t.i.d. for 2 weeks, n=6.
Arm 2: administration of azithromycin 500 mg for 3 days, tipepidine hibenzate 60 mg for 2 weeks, n=8.

6. Main outcome measures

Cough score, white blood cell count, erythrocyte sedimentation rate, and C-reactive protein (CRP) level.

7. Main results

In arm 1, cough score was significantly decreased on day 5 compared to day 1 after the first visit ($P<0.05$). In arm 2, cough score was significantly decreased on day 7 ($P>0.05$). The rate of cough score decline was significant on day 5 in arm 1 ($P<0.05$) and on day 11 in arm 2 ($P<0.05$) There were no significant differences in white blood cell count, erythrocyte sedimentation rate, and CRP level.

8. Conclusions

Combination therapy with azithromycin and bakumondoto or tipepidine hibenzate appears to be effective in the treatment of cough in patients with mycoplasmal bronchitis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

Persistent cough in mycoplasmal bronchitis is often difficult to treat. This interesting study evaluates the efficacy of bakumondoto in a randomized controlled trial. It is likely that allocation by the envelope method leads to difficulty in preserving randomization. This clinical trial investigates the efficacy of azithryomycin combined with bakumondoto or tipepidine hibenzate in treating cough in mycoplasmal bronchitis, but the investigation lacks a placebo-group as control. Furthermore, to determine the difference in efficacy between the two arms, post-administration cough scores must be compared between the two arms. In addition, some participants have persistent cough even after 2 weeks in both arms. Consideration of Kampo "*sho*" (証, pattern/syndrome) for bakumondoto is required for further studies. Future studies regarding these points, and also inclusion of male patients, are awaited.

12. Abstractor and date

Okabe T, 25 November 2008, 8 August 2009.