

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

Watanabe N, Miyazawa T. Comparative investigation of the antitussive effects of bakumondoto and tipepidine hibenzate in cases of mycoplasma bronchitis. *Kampo to Meneki-Arerugi (Kampo and Immuno-Allergy)* 2007; 21: 31-6 (in Japanese with English abstract).

Watanabe N, Nakagawa T, Miyazawa T. Examination of effective antitussive against cough caused by mycoplasma bronchitis. *Kampo to Meneki-Arerugi (Kampo and Immuno-Allergy)* 2008; 22: 63-8 (in Japanese with English abstract).

1. Objectives

To compare the efficacy of bakumondoto (麦門冬湯) with that of tipepidine hibenzate for suppressing cough in patients with mycoplasma bronchitis.

2. Design

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

3. Setting

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

4. Participants

Twenty patients with mycoplasma bronchitis who exhibited no signs of pneumonia on chest radiographs.

5. Intervention

Arm 1: azithromycin 500 mg for 3 days and TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. for 2 weeks (n=6).

Arm 2: azithromycin 500 mg for 3 days and tipepidine hibenzate 60 mg for 2 weeks (n=8).

Arm 3: azithromycin 500 mg for 3 days, tipepidine hibenzate 60 mg for 2 weeks, and TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. for 2 weeks (n=6).

6. Main outcome measures

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

7. Main results

In arms 1 and 3, cough score was significantly decreased on day 5 compared with 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 arms 1 and 3 ($P<0.05$) and on day 11 in arm 2 ($P<0.05$). The cumulative decline in cough score from day 1 to day 14 was highest in arm 3. 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 mycoplasma bronchitis. In addition, triple therapy with azithromycin, bakumondoto, and tipepidine hibenzate may be similarly effective.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

Persistent cough in mycoplasma bronchitis is often difficult to treat. This interesting study evaluates the efficacy of azithromycin combined with bakumondoto and/or tipepidine hibenzate in treating cough in mycoplasma bronchitis in a randomized controlled trial. However, it uses allocation by the envelope method (which likely leads to difficulty in preserving randomization) and lacks a placebo-group as control. Furthermore, to determine the differences in efficacy among the three arms, post-administration cough scores must be compared among the three arms. In addition, some participants have persistent cough even after 2 weeks in all three arms. In future studies, Kampo "sho" (証, pattern) should be considered for bakumondoto.

12. Abstractor and date

Okabe T, 8 December 2009, 1 June 2010, 31 December 2013.