Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine
Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

1. Infections (including Viral Hepatitis)

10. Respiratory Diseases (including Influenza and Rhinitis)

References

Watanabe N, Makino S, Nakagawa T, et al. Efficacy of bakumondoto on cough in mycoplasma infection. *Science of Kampo Medicine* 2017; 41: 116-8 (in Japanese). Ichushi Web ID: 2017285714

1. Objectives

To evaluate the efficacy of bakumondoto (麦門冬湯) on cough in mycoplasma bronchitis

2. Design

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

3. Setting

Study sites not stated (authors' institutions: a research center and clinics), Japan.

4. Participants

Twenty-four patients who presented with persistent cough, who underwent chest X-ray that excluded pneumonia findings such as ground-glass opacity, and who had an increased mycoplasma antibody titer (PA method) of 1:80 or above and thus were clinically considered as having mycoplasma bronchitis, and were started on treatment with azithromycin hydrate 500 mg once daily for 3 days.

5. Intervention

Arm 1: oral administration of TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3 g t.i.d. for 2 weeks (n=7)

Arm 2: oral administration of tipepidine hibenzate 20 mg t.i.d. for 2 weeks (n=9)

Arm 3: oral administration of TSUMURA Bakumondoto(麦門冬湯)Extract Granules 3 g plus tipepidine hibenzate 20 mg, t.i.d. for 2 weeks (n=8)

6. Main outcome measures

Change in the cough score

7. Main results

The cough score significantly decreased on day 4 in the bakumondoto group, on day 7 in the tipepidine hibenzate group, and on day 4 in the bakumondoto + tipepidine hibenzate group (P<0.05 for all).

8. Conclusion

Add-on use of bakumondoto to a macrolide antimicrobial agent is effective for cough in mycoplasma bronchitis. In particular, combination use of bakumondoto plus a central antitussive agent more promptly alleviates cough in mycoplasma infection.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

Not stated.

11. Abstractor's comments

This is a meaningful article on evaluation of the effect of bakumondoto on persistent cough as a common complaint in the context of mycoplasma infection. Drawbacks include lack of statement about the specific scale used for the cough scoring, which makes the symptomatic course assessments difficult. In addition, because of lack of intergroup comparison, assessment of the effect of the intervention with bakumondoto is also difficult. A question also remains whether mycoplasma infection can be diagnosed only from a mycoplasma PA antibody titer in single serum of 1:80 or above (rather than 1:320 or above) without a paired serum and without chest X-ray opacity. The authors concluded that combination use of bakumondoto plus a central antitussive agent is useful, but did not specify how the results led to this conclusion. Efficacy of bakumondoto on cough is generally discussed, but has rarely been investigated by RCTs, and such studies are meaningful. Future studies designed to compare symptomatic changes between treatment arms are awaited. Also, while determination of causative bacteria is often difficult in clinical practice, further studies with determination of causative organisms or evolutionary studies without determination of causative organisms would be warranted.

12. Abstractor and date

Koike H, 1 June 2020.