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

Mikamo H, Tamaya T. Usefulness of Kampo medicine for the treatment of infections from the perspective of medical economics^{*}. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2007; 24: 105-8 (in Japanese). Ichushi Web ID: 2008050180

1. Objectives

To evaluate the efficacy, impact on recurrence rate, and medical cost efficiency of antibiotics plus Kampo combination therapy for bacterial respiratory infections.

2. Design

Randomized controlled trial (RCT).

3. Setting

Obstetrics and Gynecology, Gifu University Hospital, Japan.

4. Participants

One hundred and sixteen patients diagnosed with acute bacterial respiratory infection.

5. Intervention

Arm 1: antibiotics alone group: treatment with levofloxacin for 5–10 days, n=51.

- Arm 2: antibiotics + Kampo group A: treatment with levofloxacin for 5–10 days + juzentaihoto (十全大補湯) or hochuekkito (補中益気湯) for 5–10 days, n=37.
- Arm 3: antibiotics + Kampo group B: treatment with levofloxacin for 5-10 days + kakkonto (葛根湯) or keishito (桂枝湯) or kososan (香蘇散) or 1-2 days + juzentaihoto (十全大補湯) or hochuekkito (補中益気湯) for 3-6 days, n=28.

None of the manufacturers of Kampo medicines used were specified.

6. Main outcome measures

Response rate, rate of recurrence within 7 days, and total medical cost.

7. Main results

The response rates were 96.1% in arm 1, 97.3% in arm 2, and 96.4% in arm 3; no statistically significant differences were observed. The recurrence rates were 3.9% in arm 1, 2.7% in arm 2, and 0% in arm 3; there were no significant between-group differences, although the rates were lower in arms 2 and 3. High recurrence rates were observed in cases of atypical pneumonia, caused by atypical pneumonia-related organisms. Total medical costs were significantly higher in arms 2 and 3, whereas for patients with recurrence, total costs tended to be reduced in these two arms.

8. Conclusions

Antibiotics plus Kampo combination therapy reduces the recurrence of bacterial respiratory infections. In patients infected with atypical pneumonia and prone to frequent recurrence, Kampo-combined therapy might reduce the total medical cost.

9. From Kampo medicine perspective

The drugs used in the intervention groups were selected on the basis of common applications: ephedra formulations such as kakkonto, are used to help generate body heat and sweat during the acute phase; shosaikoto is used for immune enhancement during the subacute phase; and *hozai* (補剤, formulations with tonic effects) such as hochuekkito and juzentaihoto are used during the recovery phase.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This is a very interesting RCT evaluating total medical cost as an outcome. We guess from the setting that all the participants were women. Inclusion of background factors (such as gender, age, and underlying disease) as well as standard criteria with which to evaluate outcomes (such as response and recurrence rates) would have helped readers understand the results. Also, using more uniform regimens in the intervention groups would have increased the value of the results. Further studies are anticipated to provide more data.

12. Abstractor and date

Tsuruoka K, 6 February 2009, 1 June 2010.