Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

10. Respiratory Diseases (including Influenza and Rhinitis)

References

Homma Y, Takaoka K, Yozawa H, et al. Effectiveness of mao-bushi-saishin-to in treating common cold syndrome - controlled comparative study using the sealed envelope method -. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine*) 1996; 47: 245–52 (in Japanese with English abstract). Ichushi Web ID: 1997025451 CiNii

Homma Y. Treatment of common cold by a Kampo medicine - Maobushisaishin-tou-. *Pharma Medica* 2007; 25: 19–21 (in Japanese). Ichushi Web ID: 2008035988 MOL, MOL-Lib

1. Objectives

To evaluate the effectiveness of maobushisaishinto (麻黄附子細辛湯) in relation to that of a generally available cold drug in treating common cold syndrome and in shortening the duration of symptoms.

2. Design

Randomized controlled trial (envelope method) (RCT-envelope).

3. Setting

Nineteen hospitals in Hokkaido, Japan.

4. Participants

Inpatients and outpatients aged 3 years or older who were diagnosed as having common cold syndrome (n=171).

5. Intervention

From November 1992 until March 1993.

Duration of administration was for 3 days from the onset of the symptoms or visit to the hospital, or, in cases where the symptoms persisted, until the symptoms were relieved.

Arm 1:TSUMURA Maobushisaishinto (麻黄附子細辛湯) Extract Granules, 2.5 g t.i.d. (n=83).

Arm 2: general common cold drug (contains salicylamide, acetaminophen, anhydrous caffeine, and promethazine methylenedisalicylate), 1.0 g q.i.d. (n=88).

6. Main outcome measures

Overall improvement, overall safety (adverse effects), overall usefulness, and duration (time to relief of each symptom).

7. Main results

Overall improvement

The percent of patients with moderate or greater improvement was 81.9 in arm 2 and 60.3 in arm 1. The between-group difference by U-test was significant (P<0.01).

Average days until the relief of symptoms

| | Arm 1 | Arm 2 | P < (U - test) |
|------------------|--------------------|--------------------|----------------|
| Fever | 2.8 ± 1.5 (29) | 1.5 ± 0.7 (27) | 0.001 |
| Feeling feverish | 2.5 ± 1.5 (36) | 1.8 ± 1.4 (29) | 0.021 |
| Cough and phlegm | 3.5 ± 1.7 (20) | 2.5 ± 1.2 (29) | 0.034 |

Time to relief of symptoms

Using Kaplan-Meier method, 4 symptoms (fever, pain or discomfort in the throat, coughing, and phlegm) were relieved in significantly less time in arm 2.

8. Conclusions

Maobushisaishinto has significantly better efficacy in treating common cold syndrome than a generally available cold drug.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

Blood urea nitrogen was mildly elevated in 1 patient in arm 1.

11. Abstractor's comments

Few RCTs have evaluated treatment for the common cold, even though it is a familiar and frequently occurring condition. This RCT appropriately uses average number of days until alleviation of fever, heat sensation, cough, and sputum secretion as the endpoints. In the early 1990s, researchers did not generally distinguish between primary and secondary endpoints. Hopefully future research will include comparative analysis of other Kampo prescriptions for the common cold, and include the Kampo pattern concept.

12. Abstractor and date

Fujisawa M, 9 March 2009, 1 June 2010, 31 December 2013.