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

Abe K. Outcomes of treatment for upper airway inflammation in children with Kampo medicine and Western medicine<sup>\*</sup>. *Dai 10-kai Nihon Shoni Toyo Igaku Kenkyukai Koen Kiroku (Proceedings of the 10th meeting of the Japan Pediatric Society for Oriental Medicine)* 1993; 10: 19–23 (in Japanese).

### 1. Objectives

To compare the efficacy of two different treatments (a Kampo medicine treatment and a Western medicine treatment) on influenza.

# 2. Design

Quasi-randomized controlled trial (quasi-RCT).

### 3. Setting

A pediatric and internal medicine clinic in Shimane prefecture, Japan.

# 4. Participants

Seven hundred and eighty-three children who presented with influenza at the same clinic between 1 and 28 February 1992 were allocated to two groups in the order of presentation. Hong Kong A strain was prevalent in the region at the time and Russian A strain was also present in small numbers.

# 5. Intervention

Arm 1: Kampo medicine group (manufacturer not specified; n=386): including those treated with maoto (麻黄湯) (n=200), keimakakuhanto (桂麻各半湯) (n=143), makyokansekito (麻杏甘石湯) (n=15), kakkonto (葛根湯) (n=8), keishinieppiitto (桂枝二越婢一湯) (n=8), keishinimaoitto (桂枝 二麻黄一湯) (n=4), saikokeishito (柴胡桂枝湯) (n=4), shoseiryuto (小青竜湯) (n=3), etc.

Arm 2: Western medicine group (n=397). Details of the drugs administered are not mentioned.

# 6. Main outcome measures

Number of consultations, and outcome assessed by the quantity of antibiotics used (oral and drip infusion) and incidence of asthmatic bronchitis, acute bronchitis, and pneumonia.

#### 7. Main results

The numbers of consultations were one (156 patients), two (130), three (51), four (32), five (11), six (4), seven (1), eight and nine (0), and ten (1) in arm 1 and one (190 patients), two (123), three (49), four (17), five (10), six (4), seven (3), eight (1), and nine ten (0) in the Western medicine group. There was no significant between-group difference in the number of clinic visits. Fifty-nine patients in arm 1 and 382 patients in arm 2 used oral antibiotics. Nine patients in arm 1 and 12 patients in arm 2 used intravenous antibiotics. Similar numbers of patients (9 in arm 1 and 12 in arm 2) suffered asthmatic bronchitis. The number of patients who suffered acute bronchitis was significantly lower in arm 1 than arm 2 (i.e., 12 vs 23, respectively, P=0.05). Two cases of pneumonia were diagnosed in arm 2 and none in arm 1.

# 8. Conclusions

There was no significant between-group difference in the numbers of consultations for influenza. The frequency of antibiotic use was lower in arm 1 while the severity and incidence of acute bronchitis was significantly higher in arm 2.

#### 9. From Kampo medicine perspective

The author discusses Kampo *sho* (証, pattern) in hypothetical terms, but appears to make no mention of the criteria used to select Kampo medicines for each patient.

# **10.** Safety assessment in the article Not mentioned.

# 11. Abstractor's comments

As in the summer-time cold trial, participants were allocated in the order of consultation (i.e., this was a quasi-randomized controlled trial). This trial was conducted before evidence-based medicine became widespread in Japan and before the introduction of the Consolidated Standards of Reporting Trials Statement. It is difficult to interpret the results because participants' ages or genders, details of the Western medicine interventions, the criteria for administration of the Kampo medicines, or the statistical test details are not clearly specified. For its time, it was an advanced undertaking and may be considered a valuable report.

# 12. Abstractor and date

Tsuruoka K, 31 December 2013