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

1. Infections (including Viral Hepatitis)

Reference

Seki T, Matsumoto T, Deguchi H, et al. Evaluation of the efficacy of hochuekkito in preventing MRSA colonization and infection *. Kampo Igaku (Kampo Medicine)* 1999; 23: 196-7 (in Japanese). Ichushi Web ID: 2000068588

1. Objectives

To evaluate whether hochuekkito has efficacy in preventing colonization and infection with methicillin-resistant *Staphylococcus aureus* (MRSA).

2. Design

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

3. Setting

Department of Traumatology and Critical Care Medicine, Dokkyo Medical University Koshigaya Hospital, Japan

4. Participants

Ninety-five patients admitted to the above hospital.

5. Intervention

Arm 1: treatment with hochuekkito (補中益気湯) (2.5 g, t.i.d.) per os (p.o.) or using a nasogastric tube; every day from the third day of hospitalization.

Arm 2: no treatment with hochuekkito.

6. Main outcome measures

From all patients, nasal, throat, and urine specimens were cultured for MRSA on the second hospital day, one week later, and then once a week. Sputum was also cultured from patients who underwent endotracheal intubation or tracheotomy and from those who were able to provide sputum. Similarly wound cultures were performed for patients with wound infection. When at least one culture of any specimen was positive for MRSA, the patient was considered to be MRSA-positive.

7. Main results

A total of 63 patients - 30 of 48 in arm 1 and 33 of 47 in arm 2 - withdrew from the study. Among these withdrawals, 25 patients in arm 1 and 32 in arm 2 were transferred to other wards or died, 3 received no hochuekkito, and 3 underwent no laboratory follow-up (cultures). Thus, 18 patients in arm 1 and 14 in arm 2 were examined and compared. The most common disease was trauma, followed by cerebrovascular disorder. There was no significant difference in MRSA positivity between arm 1 (8 of 18 patients) and arm 2 (9 of 14 patients). Among the trauma patients, however, there was a trend toward lower MRSA positivity in hochuekkito-treated patients (5 of 11 [45.5%] being positive), compared with hochuekkito-untreated patients (5 of 7 [71.4%] being positive). A similar trend toward lower MRSA positivity in hochuekkito-treated patients was found among patients who required mechanical ventilation.

8. Conclusions

It is suggested that administration of hochuekkito can prevent MRSA infection.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article None.

None.

11. Abstractor's comments

The authors deserve praise for conducting this RCT in an emergency care setting. Given the setting, it is not surprising that many patients (66%) withdrew from the study. But the authors' reasons for the withdrawals provide readers with very useful information. They also described gown use and hand washing by medical personnel and visitors, reflecting their consideration of bias and confounding factors. Unfortunately, this study included only a small number of patients. If it had employed a blinded, placebo-controlled design, the report would have been more reliable. The development of future studies is expected.

12. Abstractor and date

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010.