18. Symptoms and Signs

Reference

Sakiyama T, Wada E, Inoue M, et al. Study of effectiveness of goreisan suppository. *Japanese Journal of Pediatric Oriental Medicine*. 2017; 30: 33-42 (in Japanese). Ichushi Web ID: 2018110205

1. Objectives

To evaluate the effectiveness and safety of goreisan（五苓散）suppository on vomiting in pediatric infectious diseases.

2. Design

Randomized controlled trial (RCT).

3. Setting

Not stated.

4. Participants

Pediatric patients with a primary symptom of vomiting associated with acute gastroenteritis or other diseases. Patients were excluded if suppository administration was not desired by the patient or patient's guardian, or if 24 hours had passed since symptomatic onset (n=50).

5. Intervention

Arm 1: A suppository made from TSUMURA Goreisan（五苓散）Extract Granules 1 g was administered once. If vomiting showed no improvement 30 minutes later, one suppository of goreisan 1 g was additionally administered. (n=25)

Arm 2: A suppository made from lactose was administered once. If vomiting showed no improvement 30 minutes later, one suppository of goreisan 1 g was additionally administered. (n=25)

6. Main outcome measures

The frequency of vomiting after the suppository administration was assessed at 30 minutes, 1 hour, and 24 hours post dose. Other assessments included presence or absence of suppository re-administration and adverse effects of the suppository.

7. Main results

The analysis was conducted on 50 patients. Vomiting occurred within 30 minutes after suppository administration in 3 patients in Arm 1 and 3 patients in Arm 2, showing no significant difference. Vomiting occurred between 0.5 and 1 hour after the suppository administration in 3 patients in Arm 1 and 5 patients in Arm 2, showing no significant difference. Suppository re-administration was required in 3 patients in Arm 1 and 7 patients in 3 patients, showing no significant difference. Among the 10 patients given suppository re-administration, vomiting occurred within 24 hours after the re-administration in no patients in Arm 1 and 4 patients in Arm 2. Among the patients without suppository re-administration, vomiting occurred in 4 patients each in Arm 1 and Arm 2, showing no significant difference.

8. Conclusions

Goreisan 1 g suppository is likely to reduce vomiting episodes in pediatric patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

In the goreisan group, no adverse reactions were noted. In the placebo group, 1 patient had watery stools after insertion of the suppository.

11. Abstractor's comments

This article describes an important RCT that evaluated the effectiveness of intestinal administration of goreisan, often used to treat pediatric vomiting. In this study, repeated vomiting occurred in fewer patients in the goreisan group than in the placebo group, but there was no statistically significant between-group difference. As the authors state in the article, the investigators in this study were attending physicians of the participants, and therefore the placebo effect was more likely to occur. This may have made it difficult to show significant intergroup differences. In addition, the sample size could be too small to detect significant differences. This study might serve as a pilot study and it is desired that larger studies to follow will address this issue.

12. Abstractor and date

Koike H, 9 November 2019.