18. Symptoms and Signs

References

Yoshida M, Mizuno T, Mizoguchi F, et al. Efficacy of goreisan suppositories for vomiting in young children (2nd report) – a double-blind study of the hochuekkito suppository–*. *Wakan Iyaku Gakkaishi* (*Journal of Medical and Pharmaceutical Society for WAKAN-YAKU*) 1991; 7: 506-7 (in Japanese). Ichushi Web ID: 1993089053

Yoshida M. Efficacy of goreisan suppository for vomiting in young children*. *Toyoigaku* (*Japanese Journal of Oriental Medicine*) 2000; 28: 36-8 (in Japanese).

Yoshida M. Efficacy of goreisan suppository*. *Nihon Syhoni Toyo Igakkaishi* (*The Japan Pediatric Society for Oriental Medicine*) 2003; 19: 13-7. Ichushi Web ID: 2005266312

1. Objectives

To evaluate the efficacy and safety of goreisan (五苓散) for vomiting in young children.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

A single facility (the department of pediatrics of a hospital), Japan.

4. Participants

Thirty-five patients who vomited three or more times within 24 hr before visiting the pediatric department and experienced vomiting/nausea during the visit. One of these patients ejected the medicine immediately after insertion and was excluded, resulting in the inclusion of 34 patients (21 males and 13 females, aged 1 – 9 years with a mean of 3.9 years) for analysis.

5. Intervention

Arm 1: administration of a home-prepared suppository containing 1 g of TSUMURA Goreisan (五苓散) Extract Granules (n=16, 10 males and 6 females).

Arm 2: administration of a home-prepared suppository containing 1 g of TSUMURA Hochuekkito (補中益気湯) Extract Granules (n=18, 11 males and 7 females).

6. Main outcome measures

Complete response (disappearance of both vomiting and nausea); partial response (presence of nausea without vomiting); and no response (vomiting of supplied water).

7. Main results

The distribution of baseline characteristics (age, sex, underlying disease, frequency of vomiting, and complication with diarrhea) were similar between arms. Complete response, partial response, and no response were achieved in 12 (75%), 2, and 2 patients receiving goreisan, and in 5 (28%), 2, and 11 patients receiving hochuekkito, respectively. The difference between arm 1 and arm 2 was statistically significant ($P<0.05$).

8. Conclusions

Goreisan suppository reduces vomiting and nausea in young children more effectively than hochuekkito suppository.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions occurred.

11. Abstractor's comments

Goreisan is generally indicated for thirst, decreased urine output, and gastrointestinal diseases such as watery diarrhea and acute gastroenteritis with nausea, vomiting abdominal pain, headache, or edema. This study demonstrated the efficacy of goreisan suppository (in-home formulation) for reducing acute vomiting in young children. The usefulness has also been demonstrated in a multicenter, double-blind study, as mentioned below. Since the study period was in winter, the target diseases included common-cold-associated dyspepsia, winter diarrhea, vomiting, and common cold. Since it is generally difficult to administer a medicine orally or by drip infusion to young children with vomiting, the suppository is considered to be a clinically useful alternative dosage form. Therefore, it is very meaningful that this study demonstrated usefulness. However, this paper does not describe the methods of randomization and statistical analysis, which should be specified. In addition, another Kampo medicine and not a true placebo was used as the control, therefore it would be useful in the future to conduct a placebo-controlled study. Future development is expected. Notably, the formulation of goreisan extract is only approved for oral use, not for use in suppositories.

In the article by Yoshida (2003), a multicenter, case-series study with the same design and evaluation methods has also reported. The study population consisted of 87 patients (43 males and 44 females, aged 0 – 9 years with a mean of 2.4 years). Complete response was achieved in 72 patients (83%), and partial response in 2 patients. No difference in efficacy for underlying diseases was shown; complete response was achieved in 43 (88%) of 49 patients with winter infantile diarrhea, 22 (76%) of 29 patients with common-cold-associated diarrhea, and 5 (83%) of 5 patients with acute gastroenteritis. No difference in baseline characteristics was shown; there was no statistically significant difference in age, frequency of vomiting, complication with diarrhea, and use of enema between patients with complete or partial response, and patients with no response.

12. Abstractor and date

Namiki T, 15 June 2007, 1 April 2008, 8 April 2009, 1 June 2010, 31 December 2013.