

**1. Infections (including Viral Hepatitis)****References**

Yoshiya K, Nakazawa S. A controlled study of TSUMURA Saireito (柴苓湯) for rotavirus infection\*. *Nihon Shonika Rinsho (Japanese Journal of Pediatrics)*. 1992; 45: 1889-91 (in Japanese).

Yoshiya K, Nakazawa S. A controlled study of TSUMURA Saireito (柴苓湯) for rotavirus infection\*. *Dai 9-kai Nihon Shoni Toyo Igaku Kenkyukai Koen Kiroku Nihon Shoni Toyo Igakkaishi (Proceedings of the 9th meeting of the Japan Pediatric Society for Oriental Medicine)* 1993; 9: 20-3 (in Japanese).

**1. Objectives**

To evaluate the efficacy of saireito (柴苓湯) for rotavirus infection.

**2. Design**

Quasi-randomized controlled trial (quasi-RCT).

**3. Setting**

No mention of participating centers (the authors are from the Department of Pediatrics, Kobe Teishin Hospital), Japan.

**4. Participants**

Forty infants diagnosed with rotavirus infection using Rotalex.

**5. Intervention**

Patients were allocated alternately to the two treatment groups in the order of consultation.

Arm 1: one intestinal infusion of powdered TSUMURA Saireito Extract Granules (0.3 g/kg body weight) dissolved in 20 mL of warmed saline solution administered by soft catheter immediately after rotavirus diagnosis (n=20).

Arm 2: no treatment (n=20).

**6. Main outcome measures**

Number of days with diarrhea and total number of vomiting episodes compared before and after administration and between groups; number of transfusion cases and number of hospitalized cases compared between groups.

**7. Main results**

The mean number of days with diarrhea (1.3–3.4 in arm 1 and 1.1–3.6 in arm 2) was not significantly different between groups. The mean number of vomiting episodes decreased significantly from 3.6 before administration to 0.6 after administration in arm 1 ( $P < 0.01$ ), but not in arm 2 (the numbers being 3.3 and 2.8, respectively). There was no significant between-group difference in the number of transfusion cases (8 in arm 1 and 14 in arm 2) and number of hospitalized cases (2 in arm 1 and 6 in arm 2).

**8. Conclusions**

Saireito administered by intestinal infusion for rotavirus infection effectively decreases the number of vomiting episodes.

**9. From Kampo medicine perspective**

Saireito was used because it is a combination of shosaikoto (小柴胡湯), which is effective for inflammation, and goreisan (五苓散), which is effective for vomiting.

**10. Safety assessment in the article**

No adverse effects from saireito intestinal infusion were observed.

**11. Abstractor's comments**

This clinical study investigated the efficacy of saireito for vomiting and diarrhea due to rotavirus infection. Given the difficulties of following up acute infection after examination, it is a valuable study because it does follow up 40 participants with no dropouts. However, the authors do not mention whether the blood sample taken at initial consultation or the blood sample taken after drug administration was tested, making it unclear whether the presented test results were included to compare severity between groups, or to indicate there is no safety issue with saireito. It is also unclear whether the intestinal infusion itself had any effect on vomiting because the authors did not carry out intestinal infusion using saline solution alone in arm 2, although this is pointed out in the paper. Yet, the authors have devised a possibly groundbreaking therapy, which appears to have relatively few adverse effects, for a disease that has lacked a good therapy, even though it affects many infants each year in winter. A future clinical study with a better defined control group is anticipated.

**12. Abstractor and date**

Goto H, 31 December 2013.