1. Infections (including Viral Hepatitis)

Reference

Morita F, Yokokawa H, Matsuda N, et al. Comparative efficacy of goreisan and probiotics in Japanese adults with acute infectious gastroenteritis: Randomized controlled trial. *Traditional & Kampo Medicine* 2017; 4: 89–93. UMIN ID: UMIN000015875, Ichushi Web ID: 2018243887

1. Objectives

To compare the efficacy and safety of goreisan（五苓散）with that of probiotics in Japanese adults with acute infectious gastroenteritis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital (Department of General Medicine of Juntendo University Hospital), Japan.

4. Participants

Seventy-six outpatients aged ≥20 years who had diarrhea and/or vomiting caused by acute infectious gastroenteritis as evaluated by internal medicine specialists between December 2014 and December 2015. Exclusion criteria included organic gastrointestinal disease (e.g., colon cancer, inflammatory bowel disease), pregnancy, breastfeeding, and severe liver dysfunction.

5. Intervention

Arm 1: TSUMURA Goreisan（五苓散）Extract Granules 2.5 g t.i.d. orally for 5 days (n=41).
Arm 2: Probiotics (LAC-B Granular Powder; Kowa) 1 g t.i.d. orally for 5 days (n=35).

6. Main outcome measures

Primary endpoints: Duration and frequency of diarrhea and vomiting.
Secondary endpoints: Duration of concomitant symptoms including nausea, abdominal pain, fever, fatigue, and anorexia.

7. Main results

Of the 76 patients, 17 patients in Arm 1 (i.e., 14 patients without a return visit and 3 patients with bacterial gastroenteritis) and 10 patients in Arm 2 (i.e., 8 patients without a return visit, 1 patient with bacterial gastroenteritis, 1 patient who withdrew consent) were discontinued.

No significant intergroup differences were shown for the duration or frequency of diarrhea or vomiting, and also for the duration of nausea, fever, or fatigue. The duration of abdominal pain (median, 2 days [range, 1–5 days] in Arm 1 vs 3 days [range, 1–5 days] in Arm 2; P=0.02) and of anorexia (median, 2 days [range, 1–5 days] vs 2.5 days [range, 1–5 days]; P=0.01) were significantly shorter in Arm 1 than in Arm 2.

8. Conclusions

Goreisan and the probiotics had similar efficacy in the treatment of acute infectious gastroenteritis with diarrhea and/or vomiting. Goreisan may have the potential to improve the general symptoms caused by gastroenteritis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects were observed in either Arm 1 or 2.

11. Abstractor's comments

This RCT evaluated goreisan compared with probiotics in many patients with acute infectious gastroenteritis, and is of significance academically and practically. In terms of the duration and frequency of diarrhea and vomiting, which were the primary endpoints of the study, no significant differences were shown between the goreisan and probiotic groups, but the results suggested similar efficacy between goreisan and the probiotics commonly used in clinical practice. In addition, the duration of concomitant symptoms of abdominal pain and of anorexia were significantly shorter in the goreisan group, which indicates that goreisan may improve the patient's general condition. The authors indicated the need for caution when extrapolating the study results to clinical practice because of selection bias and small sample size. However, the study results appeared to be promising enough for a future multicenter clinical study.

12. Abstractor and date

Kogure T, 12 September 2019.