11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Okuno S, Hirayama K, Inoue J, et al. Effects of rikkunshito on the postoperative nausea and vomiting (PONV) after laparoscopic gynecological surgery. *Masui* (*Japanese Journal of Anesthesiology*) 2008; 57: 1502-9 (in Japanese with English abstract). CENTRAL ID: CN-00668598, Pubmed ID: 19108494 MOL, MOL-Lib

1. Objectives

To evaluate the effect of rikkunshito (六君子湯) on postoperative nausea and vomiting.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

One hundred and forty-two patients undergoing gynecological laparoscopic surgery.

5. Intervention

Arm 1: oral administration of TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g on the morning of surgery + rectal administration of 2 TSUMURA Rikkunshito suppositories (containing rikkunshito 1.5 g per suppository) during surgery + oral administration of TSUMURA Rikkunshito Extract Granules (六君子湯) 7.5 g/day postoperatively for 2 days (n=91).

Arm 2: no treatment (n=51).

6. Main outcome measures

The incidence of postoperative nausea and vomiting, changes in nausea and vomiting score, postoperative dietary intake, etc.

7. Main results

There was no significant between-group difference in the incidence of postoperative nausea and vomiting and in nausea and vomiting scores at each time point. However, the vomiting score in arm 1 was significantly lower on postoperative day 2 than on arrival at the ward and on postoperative days 0 and 1, and significantly lower on postoperative day 1 than on arrival at the ward. In contrast, vomiting score in arm 2 was significantly lower only on postoperative day 2 than on postoperative day 1. The postoperative dietary intake in arm 1 had recovered by the morning of postoperative day 2, while in arm 2, it was significantly lower until lunchtime on postoperative day 2. There were no significant between-arm differences in nausea and vomiting scores or postoperative dietary intake at each time point.

8. Conclusions

Perioperative administration of rikkunshito did not decrease the incidence of postoperative nausea and vomiting. However, this study suggests that rikkunshito may relieve nausea and vomiting and facilitate earlier recovery of dietary intake.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

In this study, the effect of Kampo medicine on perioperative symptoms was evaluated for the first time, and suppositories were used in patients unable to take medicines orally. Although there were no significant differences, the efficacy of rikkunshito was suggested. However, randomization itself and the method of randomization should be described in the article. The authors should have followed CONSORT guidelines for the conduct and reporting of RCTs. As the authors stated, more marked differences would have been observed if rikkunshito had been administered prophylactically at least 1 week before surgery. The dose of drug delivered by suppository inevitably tends to be low. Alternatively, rikkunshito could have been administered, for example, via gastric tube. However, as the induction of vomiting during extubation was a concern, suppositories were used on the day of surgery. Since rikkunshito suppositories are not usually used and alternative methods of administration have not been studied, there is no evidence to show that the suppository is the best method of drug delivery. Further evaluation by surgeons or anesthesiologists is expected.

12. Abstractor and date

Motoo Y, 1 June 2010.