11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References

Kume K, Kasuya Y, Ozaki M. Effect of Goreisan, a traditional Japanese Kampo medicine, on postoperative nausea and vomiting in gynecological patients. *JA Clinical Reports* 2017; 3: 552: 1-6. doi: 10.1186/s40981-017-0122-5 Pubmed ID: 29457096

1. Objectives

To evaluate the efficacy and safety of goreisan（五苓散）on postoperative nausea and vomiting (PONV) after gynecological surgery under general anesthesia

2. Design

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

3. Setting

One university hospital, Japan

4. Participants

Eighty-three patients aged 20 to 50 years who underwent gynecological surgery.

Exclusion criteria: American Society of Anesthesiologists Physical Status (ASA-PS) 3 or more, Body Mass Index (BMI) ≥35, pregnancy or lactation, use of other Kampo medicines, steroids, immunosuppressants, or chemotherapy agents, insufficient follow-up

5. Intervention

The following solution or water was administered through a nasogastric tube one hour before completion of the surgery:

Arm 1: Goreisan（五苓散）Extract Granules 7.5 g (manufacturer unknown) dissolved in 20 mL of water at 40°C (n=40)

Arm 2: placebo: 20 mL of water at 40°C (n=43)

6. Main outcome measures

The primary outcome measure was the incidence of PONV and the requirement of antiemetic use.

The secondary outcome measures were the incidence and severity of postoperative pain and the requirement of analgesic use.

7. Main results

The incidence of PONV during the first 2 hours after extubation was 45% in Arm 1 and 46.5% in Arm 2 ($P = 0.89$), showing no significant difference. The incidence and severity of PONV up to 24 hours after extubation showed no significant differences. Since the interim analysis showed no significant differences, the study was terminated with a sample size of 83 patients, although more patients were to be recruited.

8. Conclusion

Goreisan does not prevent PONV.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

Postoperative pain, clinical course, etc. were assessed in the goreisan and placebo groups, and showed no significant differences. The study was conducted safely.

11. Abstractor's comments

There is evidence that drugs such as 5-HT_3 receptor antagonists reduce PONV. This clinical study investigated whether goreisan has such an effect, but unfortunately found none. However, this study appears to be meaningful in that it provided a foundation for other studies (to investigate other Kampo medicines, etc.).

12. Abstractor and date

Kato Y, 1 June 2020.