## 19. Injury, Poisoning, and Postoperative Pain

**Reference**

Kuwamura A, Komasawa N, Kori K, et al. Preventive effect of preoperative administration of hange-shashin-to on postoperative sore throat: a prospective, double-blind, randomized trial. *Journal of Alternative Complementary Medicine* 2015; 21: 485-8.

**1. Objectives**

To evaluate the efficacy and safety of hangeshashinto (半夏瀉心湯) on postoperative sore throat and nausea.

**2. Design**

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

**3. Setting**

One hospital anesthesiology department, Japan.

**4. Participants**

Seventy adult females before surgery for benign gynecological disorder. Participants had been rated either class 1 (healthy apart from disorder for surgery) or class 2 (patients with mild systemic disease) on the American Society of Anesthesiologists physical status (ASA-PS), were scheduled for laparoscopic surgery under general anesthesia, and were expected to be hospitalized for at 24 hours after surgery. Gravida and women taking painkillers, anti-inflammatories, or other Kampo medications were excluded.

**5. Intervention**

Arm 1: Intervention group – TSUMURA Hangeshashinto (半夏瀉心湯) Extract Granules 2.5g per dose taken orally on the night before surgery and the morning of surgery, twice in total (n=35). The hangeshashinto was mixed with jelly.

Arm 2: Control group – Jelly only (n=35).

The pharmacy department prepared both the intervention drug and the placebo. Administration details were not revealed to the patients, anesthetists or nurses. Intratracheal intubation was carried out by an anesthetist with over 8 years experience, and the attending physician was not told the details of drug administration. A stomach tube was inserted immediately before surgery, and removed at the end of anesthesia.

**6. Main outcome measures**

The researchers recorded the presence/absence and severity of sore throat and nausea immediately after and at 3 and 24 hours after anesthesia awareness using a Numeric Rating Scale (NRS) for pain.

**7. Main results**

Incidence and severity of sore throat was significantly lower in arm 1 than arm 2 immediately after and 3 hours after surgery ($P<0.05$). However, there was no difference between arm1 and arm 2 for nausea.

**8. Conclusion**

Administration of hangeshashinto before general anesthesia significantly reduces sore throat after surgery in female patients undergoing laparoscopic surgery for a gynecological disorder. No effects are observed for hangeshashinto for postoperative nausea.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

No adverse event occurred during the clinical trial. The authors state that none of the symptoms that may be observed in hangeshashinto, namely edema, liver dysfunction, interstitial pneumonia and hypokalemia, was observed. According to the CONSORT flow chart in the original paper, there were no dropouts from this trial.

**11. Abstractor's comments**

A well designed DB-RCT. The authors precisely describe the method for determining the sample size. It can be understood from the paper that blinding was scrupulous and each person involved made independent assessments. The authors also describe in detail the stomach tube and intratracheal intubation associated with sore throat. And with the outcomes as well, the authors' use of NRS as criteria for assessment of pain is valid. The study design is therefore excellent, and the evidence for the results achieved is strong. If there is one thing that could be added, it might be more interesting to introduce a slightly longer term goal to the outcomes, for example, shortening of the period of hospitalization, etc. Further progress in this research is anticipated.

**12. Abstractor and date**

Tsuruoka K, 9 March 2017