Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

19. Post-anesthesia and Postoperative Pain

Reference

Otake T, Kato I, Saito S, et al. The prophylactic effect of "gosyuyu-to" and "gorei-san" for post-spinal headache. *Pain Clinic* 1991; 12: 648-52 (in Japanese).

1. Objectives

To evaluate the efficacy of goshuyuto (呉茱萸湯) and goreisan (五苓散) for post-lumbar puncture headache (PLPH).

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned (the authors were affiliated with the Department of Anesthesiology, Isesaki Municipal Hospital), Japan.

4. Participants

Two hundred and ninety-five American Society of Anesthesiologists (ASA) PS I or II patients who underwent lumbar anesthesia.

5. Intervention

Arm 1: treatment with TSUMURA Goreisan (五苓散) Extract Granules 2.5 g orally 4 times, at night after surgery and in the morning, at noon, and in the evening of the following day (n=88).

- Arm 2: treatment with TSUMURA Goshuyuto (呉茱萸湯) Extract Granules 2.5 g orally 4 times, at night after surgery and in the morning, at noon, and in the evening of the following day (n=93).
- Arm 3: no treatment with Kampo medicine (n=114).
 - Indomethacin suppository was the only drug used for relieving postoperative wound pain.

6. Main outcome measures

Post-lumbar puncture headache (PLPH) severity was evaluated using a 5-point scale on days 1 (24 hours after the lumbar puncture), 2, 3, and 7.

7. Main results

The incidence of PLPH in all patients was 21.4%. Two-arm comparisons of the ratings of PLPH revealed significantly greater relief in arm 2 than arm 3 only on day 1 (P<0.05). Sex-specific analysis showed significantly greater relief in the female patients of arm 2 than of arm 3 on day 1 (P<0.05).

8. Conclusions

Goshuyuto seems to be effective for preventing and relieving headache after lumbar anesthesia or after intrathecal puncture during epidural block anesthesia.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article Not mentioned.

11. Abstractor's comments

This is an interesting clinical study of the efficacy of goshuyuto and goreisan for relieving PLPH. It is a well-designed study with appropriate consideration given to clinical details including patient characteristics, interactions with indomethacin, type of puncture needle, and patient position. Since the incidence of PLPH is low and decreases over time, the small sample size may have contributed to the lack of a statistically significant difference in the outcome. In addition, if Kampo medicines had been administered for the duration of PLPH (about a week), differences among the three arms might have appeared on other days besides day 1. Despite the limited number of cases, this clinical study demonstrated the efficacy of goshuyuto. Future consideration of sample size and treatment duration would help to further clarify the efficacy of Kampo medicines for PLPH.

12. Abstractor and date

Goto H, 15 September 2008, 1 June 2010, 31 December 2013.