#### **Evidence Reports of Kampo Treatment**

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

### 9. Cardiovascular Diseases

### Reference

Yoshikawa T, Munakata S, Okuma H. Effectiveness of goreisan for recurrence prevention in elderly cases of chronic subdural hematoma surgery— Interim report on a comparative trial\*. *Noshinkei Geka to Kampo (Neurosurgery and Kampo)* 2010: 16 (in Japanese).

#### 1. Objectives

To evaluate the effectiveness and safety of goreisan (五苓散) after chronic subdural hematoma surgery in elderly people.

## 2. Design

Randomized controlled trial (RCT).

## 3. Setting

Department of Neurosurgery, Kuroishi General Hospital, Japan.

# 4. Participants

Forty-three elderly people over 70 years who underwent surgery (trephining) for symptomatic chronic subdural hematoma between January and August 2009.

#### 5. Intervention

Administration continued for 1 month from the day after surgery.

Arm 1: goreisan (五苓散) (manufacturer not identified) 7.5 g/day (administration frequency not indicated) (n=22).

Arm 2: no treatment (n=21).

Steroids, glyceol, or hemostatics were not used in combination.

## **6.** Main outcome measures

Changes in the hematoma were compared using CT scan 7, 14, and 28 days after surgery.

# 7. Main results

The age range was 73–89 years, and the between-group differences in gender or age were insignificant. The rate of hematoma shrinkage was greater in arm 1 than arm 2, especially between the 7<sup>th</sup> and 14<sup>th</sup> days (statistical significance not specified). Repeat surgery was required for 2 of the 22 participants in arm 1 (9%) and 5 of the 21 participants in arm 2 (24%), however, there was no significant between-group difference.

## 8. Conclusions

Goreisan may be effective for prevention of recurrence following chronic subdural hematoma surgery.

# 9. From Kampo medicine perspective

None.

## 10. Safety assessment in the article

No complications from goreisan were observed.

# 11. Abstractor's comments

This is a novel clinical study that investigated the effects of goreisan in preventing recurrence in elderly after chronic subdural hematoma surgery. The study was conducted to investigate goreisan's effects in preventing recurrence of postoperative chronic subdural hematoma, because it had been suggested that goreisan was effective for non-surgical cases of the condition. However, the study was presented as an abstract at a seminar, so unfortunately no details of the methods and results are included. In addition, it is an interim report, as the title indicates, so at the time it was written, it could report no significant difference recurrence rate between the goreisan group and the control group. The authors will hopefully continue with their research because the possibility remains that enlarging the sample groups will elucidate the effectiveness of goreisan, as the authors mention in their abstract. Goreisan has few adverse effects, so once it is established that it is effective for the prevention of recurrence after surgery in elderly cases of chronic subdural hematoma, a new therapeutic domain will have opened up for Kampo medicines in the field of neurosurgery. This is, therefore, a very important clinical study that holds much interest.

#### 12. Abstractor and date

Goto H, 31 December 2012