

5. Psychiatric/Behavioral Disorders**References**

Takase S. The efficacy of Yokukansan (抑肝散) on postoperative delirium after cardiovascular surgery in the elderly*. *Kampo Igaku (Science of Kampo Medicine)* 2010; 34: 132-4 (in Japanese).

Takase S, Yokoyama H. Using a Kampo medication in the perioperative period – The preventative effects of yokukansan (抑肝散) on postoperative delirium after cardiovascular surgery in the elderly*. *Kampo to Saishin-chiryō (Kampo & the Newest Therapy)* 2013; 22: 113–19 (in Japanese).

1. Objectives

To evaluate the efficacy of yokukansan (抑肝散) for postoperative delirium after cardiovascular surgery in the elderly.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Department of Cardiovascular Surgery, Fukushima Medical University Hospital, Japan.

4. Participants

Thirty patients who underwent cardiovascular surgery since April 2009.

5. Intervention

Arm 1: Administration of TSUMURA Yokukansan (抑肝散) Extract Granules 2.5 g t.i.d. from 5-7 days prior to surgery until the day of discharge except for the day of surgery (n=15).

Arm 2: No administration of yokukansan (n=15).

6. Main outcome measures

Each item on the 10-item Delirium Rating Scale-J (DRS-J) (orientation, hallucination, delusions, agitation, motor restraints, perceptual disturbances, physical disorders, sleep-wake cycle disturbance, lability of mood, fluctuation of symptom severity). Assessment by physicians of 10 items of the DRS-J at 3 days prior to surgery, and 3 and 10 days after surgery. Assessment by nurses of 6 items of the DRS-J (hallucination, agitation, motor restraints, perceptual disturbances, sleep-wake cycle disturbance, lability of mood) at 3 days prior to surgery and 1–5, 7, 10, 12, 14, and 16 days after surgery.

7. Main results

In the assessments by physicians, there were significant between-arm differences in orientation ($P=0.0033$), delusion ($P=0.021$), agitation ($P=0.0011$), and lability of mood ($P=0.0044$). In the assessments by nurses, there were significant between-arm differences in hallucination ($P=0.0383$), agitation ($P=0.0049$), and lability of mood ($P=0.0364$). Overall assessments (the total sum of the scores for all items) both by physicians and by nurses tended to improve in arm 1 more than arm 2.

8. Conclusions

Yokukansan is effective for preventing delirium after cardiovascular surgery in elderly patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Using diuretics after cardiovascular surgery makes patients susceptible to hypokalemia; however, no impacts from yokukansan administration were observed.

11. Abstractor's comments

This is an innovative clinical trial evaluating the efficacy of yokukansan for delirium after cardiovascular surgery in the elderly. It is significant that the authors used yokukansan to solve an actual clinical problem such as post-operative delirium and demonstrated its effectiveness. On the other hand, the control group included three cerebrovascular disorder patients and one patient with preoperative dementia, so the mean surgical risk score was significantly high, a circumstance that might have meant greater susceptibility to delirium. Considering that the envelope method was used to allocate participants, it may have been better if the allocation was randomized more rigorously. Nevertheless, this interesting clinical study provides a helpful perspective for a future large-scale study assessing the efficacy of yokukansan for preventing postoperative delirium in the elderly.

12. Abstractor and date

Goto H, 25 December 2010, 31 December 2013, 6 June 2015.