Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

5. Psychiatric/Behavioral Disorders

Reference

Egawa H, Hamaguchi S. Clinical applications of Kampo medications – Clinical applications of Kampo medications for Postoperative Cognitive Dysfunction (POCD) – Yokukansan and perioperative management of fracture of the proximal femur in the elderly.^{*} *Nou* 21 (*Brain* 21) 2015; 18: 271-4.

1. Objectives

To evaluate the effectiveness of yokukansan (抑肝散) for cognitive dysfunction after surgery for fracture of the proximal femur/ in the elderly.

2. Design

Randomized controlled trial (RCT).

3. Setting

Centers not mentioned. (The authors are from the Pain Clinic and Department of anaesthesiology), Japan

4. Participants

Forty patients, 70-years or older scheduled for femoral neck fracture surgery.

5. Intervention

Arm 1: Yokukansan (抑肝散) 7.5g/day (manufacturer and administration frequency not mentioned) taken orally for 7-14 days then surgery and a further 3 weeks administration (n=20).

Arm 2: No administration (n=20).

6. Main outcome measures

Cognitive function test (Mini-Mental State Examination: MMSE) combined with 3-item Nishimura Mental State Scale for the Elderly (NMS); days hospitalized (before surgery); and cognitive function on days 1, 3, 5, 7, 10, 14, and 21 after surgery.

7. Main results

MMSE was 3.3 ± 1.0 and NMS was 5.6 ± 1.2 on day 1 after surgery in both Arms 1 and 2, which was a significant decrease compared to presurgery (*P*<0.01). MMSE improved significantly from day 3 to 7 after surgery in arm 1 compared to arm 2 (*P*<0.05), but there was no difference in NMS between groups. A significant improvement was found in arm 1 compared to arm 2 for both MMSE and NMS from day 7 to 21 after surgery (*P*<0.05).

8. Conclusion

Yokukansan suppresses the decrease in cognitive function after surgery for fracture of the proximal femur in elderly patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

This is a very interesting clinical study of the application of yokukansan, which is frequently used for elderly dementia patients, to decreased cognitive function after surgery in the elderly. However, perhaps because it is a short paper, the authors did not mention any background factors in either group such as gender or primary disease, and they did not describe the administration methods or details of whether there were any dropouts, etc. In addition, it would appear that there was a difference in MMSE on day 1 after surgery, while the authors asserted that taking yokukansan improved MMSE from day 3 after surgery compared to the non-administration group. There is the possibility that administration of yokukansan before surgery affected this difference, so, to clarify the postsurgery effects, the authors would have preferably measured MMSE and NMS immediately before surgery. Nevertheless, the study suggests that yokukansan improves cognitive function after surgery for fracture of the proximal femur, so hopefully those details will be clearly articulated and it will be widely used in clinical practice.

12. Abstractor and date

Goto H, 31 December 2016