## 5. Psychiatric/Behavioral Disorders

**Reference**

Suzuki T, Futami S, Igari Y, et al. A Chinese herbal medicine, choto-san, improves cognitive function and activities of daily living of patients with dementia: A double-blind, randomized, placebo-controlled study. *Journal of the American Geriatrics Society* 2005; 53: 2238-40. CENTRAL ID: CN-00554102, Pubmed ID: 16398922

**1. Objectives**

To evaluate the efficacy of chotosan (釣藤散) for improvement of cognitive function and activities of daily living in dementia patients.

**2. Design**

Double-blinded randomized controlled trial (DB-RCT).

**3. Setting**

Not mentioned (authors belong to Department of Geriatric Medicine, Nippon Medical School Hospital, and another hospital), Japan.

**4. Participants**

Thirty patients with mild or moderate dementia: 13, Alzheimer type dementia (MMSE[1] score 14 – 25) and 17, Alzheimer disease (MMSE score 10 – 21) or cerebrovascular disorders (MMSE score not indicated). All were included in the analysis population.

[1]MMSE: Mini-Mental State Examination

**5. Intervention**

Arm 1: oral administration of 2.5 g of TSUMURA Chotosan (釣藤散) Extract Granules t.i.d. before meals for 8 weeks (n=10).

Arm 2: oral administration of 2.5 g of TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules t.i.d. before meals for 8 weeks (n=10).

Arm 3: oral administration of 2.5 g of placebo t.i.d. before meals for 8 weeks (n = 10).

**6. Main outcome measures**

Cognitive function evaluated by the MMSE; activities of daily living, by Barthel Index (BI); and caregiver burden, by Zarit Caregiver Burden Scale (Z score).

**7. Main results**

In arm 1, a significant improvement over baseline was observed in MMSE score, from 15.5±4.0 to 17.5±4.9, and BI, from 67.5±34.6 to 71.5±35.8, whereas no such improvement was seen in arm 2 or 3. There was no significant difference in Z score among the 3 arms.

**8. Conclusions**

Chotosan improves cognitive function and activities of daily living in dementia patients.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned

**11. Abstractor's comments**

This study, which investigated the efficacy of chotosan and goshajinkigan for cognitive function and activities of daily living in elderly patients with dementia in a double-blind RCT, provides high-quality evidence. Although the sample size was small and no statistically significant difference between the arms was found, cognitive function and activities of daily living were significantly improved over baseline in the chotosan group. However, no baseline characteristics except for age and sex are indicated, the underlying disease is not mentioned, and MMSE scores of patients with cerebrovascular disorders are not given. Patient characteristics and each score should be provided. Furthermore, MMSE score in the chotosan group was improved over baseline, but the level after 8-week dosing was almost equal to that in the placebo group (presumably because there was a significant difference in MMSE score at baseline between 2 groups). A future investigation of the efficacy of chotosan for improving cognitive function and activities of daily living is expected with a larger sample size and for a longer period.

**12. Abstractor and date**

Goto H, 15 June 2007, 1 April 2008, 1 June 2010.