5. Psychiatric/Behavioral Disorders

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1. **Objectives**
   To evaluate the efficacy and safety of yokukansan (抑肝散) for treating behavioral disorders and improving activities of daily living in dementia patients.

2. **Design**
   Randomized controlled trial (RCT).

3. **Setting**
   Three hospitals (long-term care facilities), Japan.

4. **Participants**
   A total of 60 patients with dementia due to Alzheimer’s disease, cerebrovascular disorder, or Lewy body disease, having a Mini-Mental State Examination (MMSE) score of <24 and a neuropsychiatric inventory (NPI) score of >6; of these, 52 patients were included for analysis.

5. **Intervention**
   Arm 1: oral administration of 7.5 g/day of TSUMURA Yokukansan (抑肝散) Extract Granules in 3 divided doses before meals for 4 weeks (n=27).
   Arm 2: untreated control group (n=25).

6. **Main outcome measures**
   MMSE score, Barthel Index, and NPI score.

7. **Main results**
   No changes were found in MMSE score in either group. Significant improvements (compared with baseline) were observed in Barthel Index, from 56.4±34.2 to 62.9±35.2, and NPI score, from 37.9±16.1 to 19.5±15.6, in arm 1. In NPI subscales for hallucination, anxiety/excitement, etc., significant improvements over baseline were noted in arm 1. Additional treatment with tiapride hydrochloride, a dopamine D1 selective neuroleptic, was required in 11 patients in arm 2 but in none in arm 1.

8. **Conclusions**
   Yokukansan is effective for improvement of behavioral disorders and activities of daily living in dementia patients.

9. **From Kampo medicine perspective**
   None.

10. **Safety assessment in the article**
    Dizziness and impaired postural sway were reported in 6 patients (54.5%) treated with tiapride hydrochloride. Two patients (7.4%) who continued yokukansan after the end of the observation period became oversedated but recovered with a reduced dose.

11. **Abstractor’s comments**
    This study, which investigated the efficacy of yokukansan for cognitive function and activities of daily living in elderly dementia patients in an RCT, provides high-quality evidence. However, the same nurses who rated MMSE and NPI scores, and Barthel Index may also have administered yokukansan, suggesting the possibility of a lack of blinding, which may have affected evaluations. In future, the effects of yokukansan in dementia patients are expected to be studied over a longer term.

12. **Abstractor and date**