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

Tanaka H. Problems and approaches to treatment of psychosomatic disease by an otorhinolaryngologist, and Kampo treatment for psychosomatic cases with depressive tendency – Focusing on kamikihito (加味 帰脾湯) –. *Phil Kampo* 2014; 47: 20-2. Ichushi Web ID: 2014238207

## 1. Objectives

To evaluate the efficacy and safety of kamikihito (加味帰脾湯) and kamishoyosan (加味逍遙散) for otorhinolaryngological symptoms with a strong psychosomatic element.

# 2. Design

Quasi-randomized controlled trial (quasi-RCT).

## 3. Setting

Single facility (hospital otorhinolaryngology department).

#### 4. Participants

Thirty patients who presented at the otorhinolaryngology department with dizziness, tinnitus or hypopharyngeal globus sensation; who scored at least 11 points on the Toho University Self-Rating Questionnaire for Depression, SRQ-D; and whose psychosomatic factors appeared to aggravate symptoms.

## 5. Intervention

Arm 1: Kamikihito (加味帰脾湯) (manufacturer and dose unknown) taken for four weeks then kamishoyosan (加味逍遙散) (manufacturer and dose unknown) taken for four weeks (n=15).

Arm 2: Kamishoyosan (加味逍遙散) (manufacturer and dose unknown) taken for four weeks then kamikihito (加味帰脾湯) (manufacturer and dose unknown) taken for four weeks (n=15).

## 6. Main outcome measures

Change in chief complaint following the change of Kampo medication.

## 7. Main results

Efficacy was relatively high in 6.7% and low in 33.3% of patients in arm 1 after the change of Kampo medication. Efficacy was not high in any and it was low in 50.0% of the 10 patients who scored 16 or more on the SRQ-D, which is an indicator of possible depression. Of the 5 patients who scored 11-15 on the SRQ-D, which is on the borderline of depression, efficacy was high in 20.0% and it was not low in any patient. In arm 2, efficacy was high in 26.7% and low in 6.7% of patients. Of the 10 patients who scored 16 or more on the SRQ-D, efficacy was high in 40.0% and it was not low in any patient. Of the 5 patients who scored 11-15 on the SRQ-D, efficacy was high in 40.0% and it was not low in any patient. Of the 5 patients who scored 11-15 on the SRQ-D, efficacy was not high in any and it was low in 20.0%.

# 8. Conclusions

Kamikihito was more effective than kamishoyosan for dizziness, tinnitus and hypopharyngeal globus sensation aggravated by psychosomatic factors in patients with an SRQ-D score of 16 or more and kamishoyosan was more effective than kamikihito in patients with an SRQ-D score of 11-15.

# 9. From Kampo medicine perspective

Kamikihito appears to be more appropriate than kamishoyosan for patients with severe depressive tendency.

#### **10.** Safety assessment in the article

No adverse effect induced by kamishoyosan or kamikihito was observed.

#### **11.** Abstractor's comments

This study was a cross-over comparison to evaluate whether kamikihito or kamishoyosan is more effective for otorhinolaryngological symptoms in which psychosomatic factors exist. The study suggests that kamikihito is effective for patients with severe depression and that kamishoyosan is effective for patients with slightly mild depression. It suggests that the SRQ-D could be a tool when selecting these two prescriptions. However, this study alone does not conclusively prove that kamikihito and kamishoyosan are effective for otorhinolaryngological symptoms. As the next stage of research to clarify which patient group responds to kamikihito and kamishoyosan, the author should prospectively study in a randomized controlled trial whether kamikihito is effective for patients with severely depressive otorhinolaryngological symptoms.

# 12. Abstractor and date

Koike H, 31 March 2017.