#### **Evidence Reports of Kampo Treatment**

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.

## 6. Nervous System Diseases (including Alzheimer's Disease)

#### Reference

Murase K, Toyama Y, Harada Y, et al. Evaluation and comparison of the effect of two Chinese herbal medicines (Bofu-tsusho-san and Dai-saiko-to) on metabolic disorders in obstructive sleep apnea patients. *American Journal of Respiratory and Critical Care Medicine* 2013; 187: A5694. CENTRAL ID: CN-00870751

### 1. Objectives

To evaluate the lipid lowering and antihypertensive effects of bofutsushosan (防風通聖散) and daisaikoto (大柴胡湯) for patients with obstructive sleep apnea as a complication of obesity and hypertension.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Not mentioned (the corresponding author belongs to the Faculty of Medicine, Kyoto University, Japan).

#### 4. Participants

One hundred and twenty-eight obstructive sleep apnea patients with hypertension and obesity remaining after at least six-month CPAP treatment.

#### 5. Intervention

Arm 1: Bofutsushosan (防風通聖散) (manufacturer unknown) for six months (n=65).

Arm 2: Daisaikoto (大柴胡湯) (manufacturer unknown) for six months (n=63).

### 6. Main outcome measures

Body mass index (BMI), blood pressure.

## 7. Main results

The patients who completed the study were 44 in arm 1 and 41 in arm 2. BMI decreased significantly in arm 1 from  $34.6\pm6.3$  kg/m² before treatment to  $33.7\pm6.6$  kg/m² after six months of treatment, while in arm 2 the scores were  $34.9\pm7.9$  kg/m² before administration and  $34.9\pm8.1$  kg/m² after six months. Although in statistical terms no antihypertensive effect with a significant difference between groups was found, a decrease in morning systolic blood pressure was observed in home blood pressure measurements in arm 1 (from  $143.3\pm13.4$  mmHg to  $138.7\pm13.9$  mmHg, P=0.03) and a decrease in diastolic blood pressure was observed in arm 2 (from  $84.3\pm10.4$  mmHg to  $80.2\pm11.1$  mmHg, P<0.01). A decrease in sleep onset latency was observed.

### 8. Conclusions

The results suggest bofutsushosan (防風通聖散) and daisaikoto (大柴胡湯) have lipid lowering and antihypertensive effects for patients with obstructive sleep apnea as a complication of obesity and hypertension.

# 9. From Kampo medicine perspective

None.

# 10. Safety assessment in the article

Not mentioned.

# 11. Abstractor's comments

Having evaluated the lipid-lowering and antihypertensive effects of bofutsushosan and daisaikoto for patients with obstructive sleep apnea as a complication of obesity and hypertension, the authors' interim report suggests that bofutsushosan has a BMI-lowering action. While no significant antihypertensive effect was observed between the two groups, blood pressure measurements taken in the morning with a home sphygmomanometer suggest a decrease in systolic blood pressure in the bofutsushosan group, and a decrease in diastolic blood pressure in the daisaikoto group. As this paper is an interim report, completion of the trial must be awaited for the final results.

## 12. Abstractor and date

Okabe T, 6 June 2015.