

## **The comparison of the effect of two Chinese herbal medicines (Bofu-tsusho-san and Dai-saiko-to) on metabolic disorders in obstructive sleep apnea patients with sustained obesity and hypertension.**

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### **Background and aim**

Obstructive sleep apnea (OSA) is one of the risk factors of metabolic syndrome and the treatments of OSA are reported to ameliorate metabolic syndrome. However, in majority of cases, the components of metabolic syndrome such as hypertension and obesity are sustained and further treatments are necessary. Although both of two Chinese herbal medicines, Bofu-tsusho-san (BF) and Dai-saiko-to (DS), were reported to have the effect on obese and hypertension, more sufficient evaluations of the efficacy and safety of these medications are required.

### **Methods**

We recruited the OSA patients diagnosed by polysomnography in twelve institutions all over Japan. Even after six months of treatment of OSA, if the patients had obesity (Body mass index (BMI)  $\geq 25$

kg/m<sup>2</sup>) and hypertension (systolic blood pressure  $\geq$ 130mmHg or diastolic blood pressure  $\geq$ 80mmHg), they were invited to the study. After enrollment to the study, they were randomized to take BF or DS for six months. We evaluated the clinical outcomes after six months in each patient.

### **Results**

As of the end of June, 2012, 128 patients were enrolled. Sixty five patients (Age 53.8 $\pm$ 10.7 years, BMI 32.7 $\pm$ 5.6 kg/m<sup>2</sup>) were randomized to BF and 63 (Age 55.9 $\pm$ 11.3 years, BMI 32.9 $\pm$ 6.8 kg/m<sup>2</sup>) were randomized to DS. Forty nine (25 BF and 24 DS) of them completed the study course. As the interim results, although the significant differences of the effects on obesity and hypertension between two medications were not found, BF showed the trend to decrease BMI (34.8 $\pm$ 6.3 to 34.4 $\pm$ 6.3 kg/m<sup>2</sup>, p=0.06) and DS showed the trend to decrease morning diastolic blood pressure (81.9 $\pm$ 10.3 to 78.9 $\pm$ 11.8 mmHg, p=0.09).

### **Conclusions**

Our interim results suggest the possibility of the therapeutic effect of BF and DS on the metabolic syndrome in patients with OSA.