9. Cardiovascular Diseases

Reference

Azushima K, Tamura K, Haku S, et al. Effects of the oriental herbal medicine Bofu-tsusho-san in obesity hypertension: a multicenter, randomized, parallel-group controlled trial (ATH-D-14-01021.R2) . *Atherosclerosis* 2015; 240: 297-304.

1. Objectives

To verify the effectiveness of the combined use of bofutsushosan (防風通聖散) with Western medical treatments for obesity hypertension patients using Ambulatory Blood Pressure Monitoring (ABPM).

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital nephrology/hypertension department, 3 hospital nephrology departments, 1 clinic, Japan.

4. Participants

One hundred and six obesity hypertension patients with a BMI of at least 25kg/m^2, aged between 20 and 79 years, who underwent antihypertensive treatment including diet and exercise therapy for at least 4 weeks before the start of the trial.

5. Intervention

Arm 1: Antihypertensive treatment including diet and exercise therapy in addition to bofutsushosan (2.5g/day at first taken orally between or before meals, with the dosage titrated as appropriate according to symptoms, up to a maximum of 7.5g/day. Manufacturer's name not mentioned) for 24 weeks (n=54).

Arm 2: Antihypertensive treatment including diet and exercise therapy without bofutsushosan (n=52).

6. Main outcome measures

The primary endpoints were hypotensive effect (using ABPM, means and short-term variability of systolic and diastolic phases and BPM at daytime and nighttime), and the secondary endpoints were the between-group differences in BMI, etc. at weeks 12 and 24.

7. Main results

After excluding dropouts, the authors analyzed 93 participants at week 12 and 88 at week 24. There was no significant difference in ABPM at week 12. In week 24, the mean diastolic phase blood pressure in daytime was significantly lower in the control group (P=0.045), and systolic blood pressure variability in daytime was significantly lower in the bofutsushosan group (P=0.006). BMI was significantly lower in the bofutsushosan group in both weeks 12 and 24 (P=0.005 and P=0.029 respectively).

8. Conclusion

Adding bofutsushosan to an anti-hypertensive agent improves short-term blood pressure variability and has an anti-obesity effect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

2 out of 54 participants (3.7%) who took the additional bofutsushosan experienced an adverse effect.

11. Abstractor's comments

This paper verified the effectiveness of adding bofutsushosan to a usual anti-hypertensive drug for patients with hypertension associated with obesity and reasons that short-term variability in blood pressure decreases with bofutsushosan. However, the authors listed 24 primary endpoints and compared 2 groups, indicating a difference of P<0.05 in effectiveness for systolic phase blood pressure variability in the daytime in the group that took additional bofutsushosan, and on the other hand, effectiveness in the control group for mean blood pressure in the diastolic phase in daytime for the other group of P<0.05, although coming to an overall conclusion for the paper that bofutsushosan is effective, is not statistically possible. It is also unclear in this study whether bofutsushosan affected blood pressure, as the authors do not describe any anti-hypertensive drug coordination. The study is significant as an exploratory study, so further research to verify that bofutsushosan decreases short-term blood pressure variability is anticipated. The paper also indicates an anti-obesity effect for bofutsushosan, although as a secondary endpoint. Further research examining its effectiveness with greater reliability is anticipated.

12. Abstractor and date

Koike H, 15 February 2017.