4. Metabolism and Endocrine Diseases

Reference

Namiki T. Basic and clinical investigation of the effect of Kampo medicines on arteriosclerosis*. *Uehara Kinen Seimei Kagaku Zaidan Kenkyu Hokokushu* (*Research Reports of Uehara Memorial Foundation*) 2007; 21: 60-3 (in Japanese). Ichushi Web ID: 2008156867

1. Objectives

To evaluate the anti-obesity effect of bofutsushosan (防風通聖散) extract granules in obese patients and the course of high-sensitivity C-reactive protein (HS-CRP) as an arteriosclerosis-promoting factor.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

The outpatient department of internal medicine at a general hospital, Japan.

4. Participants

Patients who were obese (body mass index [BMI] of 25 or greater), hypertensive (diastolic blood pressure of 90 mmHg or higher and/or a systolic blood pressure of 140 mmHg or higher), treatment-naïve or taking oral antihypertensives, and aged ≥20 to <80 years were included after giving written informed consent. Exclusion criteria were: 1) serious complications (cardiac disease, renal disease, malignancy, etc.); 2) use of medications that might affect the outcome of this trial; 3) pregnant, lactating, or likely to become pregnant; and 4) considered ineligible by the investigator.

5. Intervention

Arm 1: bofu group: conventional therapy plus oral administration of bofutsushosan (防風通聖散) extract granules (manufacturer, not specified) 7.5 mg/day before or between meals for 12 weeks in 25 patients (16 males and 9 females; mean age, 63.3±12.3 years).

Arm 2: control group: continuation of conventional therapy in 30 patients (19 males and 11 females; mean age, 64.2±10.3 years).

6. Main outcome measures

1) Body weight, BMI, blood pressure, pulse; 2) levels of fasting blood glucose, hemoglobin a1c (Hba1c), and insulin; 3) levels of total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglyceride; 4) visceral fat (measured by computed tomography [CT]); and 5) blood biochemistry including HS-CRP level, hepatic and renal functions, and electrolyte levels. 1) to 3) were measured at weeks 0, 4, 12, and 24; 4) at weeks 0 and 24; and 5) at weeks 0, 4, 8, 12, and 24.

7. Main results

Body weight was reduced by 1.16 kg (–1.5%) (from 77.82±17.53 kg at week 0 to 76.63±17.66 kg at week 24) in the bofu group, in contrast to the reduction of 1.49 kg (–2.8%) (from 71.79±10.16 kg at week 0 to 70.30±10.36 kg at week 24) in the control group. But the between-group difference was not significant. BMI was decreased by 1.6% (from 30.62±5.81 at week 0 to 30.14±5.78 at week 24) in the bofu group and 2.1% (from 27.80±2.56 at week 0 to 27.22±2.79 at week 24) in the control group.

HS-CRP was 1199.00±1040.46 μg/dL at week 0, then gradually increased by 914.54 μg/dL to 2113.54±4524.08 μg/dL at week 24 in the control group, while it was 2918.17±4239.03 μg/dL at week 0, transiently increased to 5229.26±11066.85 μg/dL at week 4, then decreased to 2694.92±3606.66 μg/dL at week 24 (decrease of 223.25 μg/dL from the week 0 level) in the bofu group.

8. Conclusions

Although body weight and BMI were higher in the bofu group than in the control group, HS-CRP at week 24 was decreased in the bofu group and increased in the control group.

9. From Kampo medicine perspective

As a basic evaluation, the anti-arteriosclerosis effect of keishibukuryogan is also described in this paper.

10. Safety assessment in the article

None.

11. Abstractor's comments

This study is an RCT that used HS-CRP as an outcome measure to evaluate arteriosclerosis. The study is very interesting in that it used a novel approach to assess a Kampo medicine. Although results on body weight and BMI were negative, further studies are expected to reveal some positive effects.

12. Abstractor and date

Tsuruoka K, 26 January 2009, 1 June 2010.