18. Symptoms and Signs

References

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1. Objectives

To evaluate the efficacy and safety of bofutsushosan (防風通聖散) in obese Japanese women with impaired glucose tolerance.

2. Design

Double-blind randomized controlled trial (DB-RCT).

3. Setting

An university hospital (Kyoto Prefectural University of Medicine), Japan.

4. Participants

Eighty-one obese women (mean body mass index, 36.5 kg/m^2) with impaired glucose tolerance were included. Patients with kidney, heart and/or liver disease, any metabolic or endocrine disease, psychiatric disorders, or cancer were excluded.

5. Intervention

Arm 1: treatment with TSUMURA Bofutsushosan (防風通聖散) Extract Granules for 24 weeks + low-calorie diet (1,200 kcal) + exercise therapy (300 kcal) (44 patients; of these, 41 were included for analysis).

Arm 2: treatment with placebo for 24 weeks + low-calorie diet (1,200 kcal) + exercise therapy (300 kcal) (41 patients; of these, 40 were included for analysis).

6. Main outcome measures

Body weight, the proportion of body fat (% weight), visceral and subcutaneous fat accumulation, systolic and diastolic blood pressure, heart rate, biochemical data (triglyceride, total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, uric acid, glycosylated hemoglobin (HbA1c), and fasting glucose), and waist and hip circumference were measured before treatment, and after 12 and 24 weeks of treatment. Values for 2-h oral glucose tolerance test (OGTT) glucose, glucose area under the curve (AUC) 120, fasting insulin, insulin AUC120, and homeostasis model assessment of insulin resistance (HOMA-IR) were measured or calculated after 24 weeks.

7. Main results

Waist circumference decreased in both arms after 12- and 24-week treatment compared with before treatment. The decrease was significantly greater after 24 weeks in Arm 1 compared with Arm 2. There were significant differences in more measures after 24 weeks than after 12 weeks in both arms. In Arm 2, body weight, body fat (%), and subcutaneous fat decreased only after 24 weeks; systolic and diastolic blood pressure, triglyceride, and total cholesterol reduced after 12 and 24 weeks. In Arm 1, body weight, body fat (%), visceral and subcutaneous fat, systolic and diastolic blood pressure, biochemical data (LDL cholesterol, HDL cholesterol, uric acid, and insulin [fasting and AUC120]), 2-h OGTT glucose, and HOMA-IR improved after 24 weeks. The decrease in body weight in Arm 1 was associated with decreased visceral and subcutaneous fat but not with a decrease in adjusted resting metabolic rate, whereas the weight loss in Arm 2 was not associated with decreased visceral fat.

8. Conclusions

Bofutsushosan is useful in the treatment of obese patients with impaired glucose tolerance.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There was no effect on cardiovascular or central nervous system in the two arms. Although no subject had steatorrhea, 3 subjects in the bofutsushosan arm discontinued treatment and withdrew from the study because of diarrhea. One subject in the placebo arm dropped out of the study owing to noncompliance.

11. Abstractor's comments

This DB-RCT (examining the efficacy and safety of bofutsushosan in obese Japanese women with impaired glucose tolerance) provides a high quality of evidence. Although body weight tended to decrease between 12 and 24 weeks of treatment in the placebo arm, it can still be concluded that the anti-obesity effect of bofutsushosan combined with diet and exercise therapies is more likely to persist potently. Further studies should be conducted to evaluate the effect of bofutsushosan monotherapy without diet and exercise therapies. Investigations with Kampo diagnostic considerations are also needed.

12. Abstractor and date

Namiki T, 15 Septmber 2007, 1 April 2008, 13 March 2009, 1 June 2010, 31 December 2013.