4. Metabolism and Endocrine Diseases

References

Uebaba K, Xu F. Association between the SNP in sympathetic β3-adrenergic receptor gene and the efficacy of bofutsushosan[*] *Nihon Toyo Igaku Zasshi* (*Kampo medicine*) 2003; 54: S225.

Kamohara S, Kawakami T, Uebaba K, et al. A study on the development of individualized medicine for the prevention, diagnosis, and treatment of metabolic syndrome using an integrative approach[*]. *Ikagaku Oyo Kenkyu Zaidan Kenkyu Hokoku* (*Research Papers of the Suzuken Memorial Foundation*) 2009; 26: 399–403.

Xu FH, Uebaba K, Ogawa H, et al. Personalized effects of a Kampo herbal formulation on metabolism — A randomized, double-blind, placebo controlled study of bohutusei-san — — *Toho Igaku* (*Eastern Medicine*) **2012; 28: 37-59 (in Japanese).**

1. **Objectives**

   To evaluate whether bofutsushosan (防風通聖散) reduces obesity.

2. **Design**

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

3. **Setting**

   Medical institutions in Toyama Prefecture, Japan.

4. **Participants**

   Invitation letters were sent to 2000 residents aged 55–65. Totally 120 subjects without diarrhea, cardiac disease, and serious hepatic or renal disease (as determined by history-taking, blood test, and electrocardiography data) were selected from obese individuals (BMI≥25) who consented to participate.

5. **Intervention**

   Arm 1: Kanebo Bofutsushosan (防風通聖散) Extract Fine Granules 3.75 g b.i.d. at least 1 hour after meals for 2 months (n=70).

   Arm 2: Indistinguishable placebo containing 5% Kanebo Bofutsushosan (防風通聖散) Extract Fine Granules with the same taste, smell, and color, and administered in the same manner as arm 1 (n=50).

6. **Main outcome measures**

   WHOQOL-26, Oriental medicine questionnaire, serum biochemical indices, IRI (immunoreactive insulin), and homeostasis model assessment-insulin resistance (HOMA-R) were measured at baseline, 2, 4, and 8 weeks.

7. **Main results**

   The data from 112 subjects (67 in arm 1 and 45 in arm 2) who completed the study were included in the analysis. The male/female ratio was 19/48 and 11/34 for arms 1 and 2, respectively. A total of 36 subjects (18 in arm 1 and 18 in arm 2; 32.1%) had a single nucleotide polymorphism (SNP) in β3-adrenergic receptor gene (18 Arg hetero in arm 1 and 15 Arg hetero and 3 Arg homo in arm 2). There was a significant between-arm difference ($P<0.05$) with demonstrated weight loss of 0.8 kg in arm 1 versus 0.1 kg in arm 2. Comparison of the responders (15 subjects: weight loss ≥ 1.5 kg) with the non-responders (16 subjects: weight loss ≥ 0.1 kg) in arm 1 demonstrated higher blood pressure and serum total protein before administration in arm 1 than arm 2, with 140 mm Hg the threshold for high blood pressure classification. This indicates that multiple regression analysis of initial blood pressure values and serum total protein values can be used to predict weight loss attributable to Bofutsushosan. Decreases in total cholesterol values at eight weeks compared to values before administration in arm 1 demonstrated a significant difference ($P<0.05$) in the high cholesterol group only. No differences in weight loss by the presence or absence of SNP were found.

8. **Conclusions**

   Bofutsushosan appears to reduce body weight in obese individuals aged 55–65.

9. **From Kampo medicine perspective**

   The results suggest that bofutsushosan is effective for obese individuals with high blood pressure and high serum total protein. This presumably equates to excess pattern and supports the classical literature..

10. **Safety assessment in the article**

    None.

11. **Abstractor's comments**

    An important DB-RCT that tested the effectiveness of bofutsushosan for obese individuals. The original paper on which was based the brief paper published as Kamohara at al. (2009) and Uebaba et al. (2003). It deserves recognition for following the CONSORT recommendations. An RCT of bofutsushosan examining excess pattern holds promise, as suggested in 'From Kampo medicine perspective'.

12. **Abstractor and date**

    Tsuruoka K, 1 June 2010, 31 December 2013.