4. Metabolism and Endocrine Diseases

Reference

Lee S J, Bose S, Seo J-G, et al. The effects of co-administration of probiotics with herbal medicine on obesity, metabolic endotoxemia and dysbiosis: A randomized double-blind controlled clinical trial. *Clinical Nutrition* 2014; 33: 973-81. Pubmed ID: 24411490

1. Objectives

To evaluate the effects of co-administration of probiotics with bofutsushosan (防風通聖散) on obesity.

2. Design

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

3. Setting

One university hospital in Seoul, the Republic of Korea.

4. Participants

Fifty females aged 19 to 65 years with BMI of >25 kg/m^2 and waist circumference of >85 cm. Exclusion criteria were hypothyroidism, Cushing's syndrome, heart diseases, cancer, lung diseases, severe renal dysfunction (Cr >2.0 mg/dL), hepatic dysfunction, non-insulin dependent diabetes mellitus (fasting blood sugar level [FBS] >140 mg/dL), eating disorders, pregnancy, breast feeding, and body weight decrease by 10% within 6 months of the study.

5. Intervention

Arm 1: TSUMURA Bofutsushosan (防風通聖散) Extract Granules 3 g b.i.d. + probiotics twice daily (Duolac7 capsules) for 8 weeks (n=25).

Arm 2: TSUMURA Bofutsushosan (防風通聖散) Extract Granules 3 g b.i.d. + placebo twice daily (identical to Duolac7 capsules) for 8 weeks (n=25).

6. Main outcome measures

The main outcome measures were body weight and gut permeability. The secondary outcome measures were BMI, blood pressure, blood parameters (e.g., lipid levels), fecal bacteria count, endotoxin level, body fat level (as measured by bioelectrical impedance), and quality of life (as measured using the Korean version of obesity-related quality of life [KOQOL] scale). In the article, parameters including body weight, waist circumference, BMI, and body fat level (bioelectrical impedance) were termed “body composition parameters,” while other parameters including blood parameters, fecal bacteria count, and endotoxin level were termed “metabolic biomarkers.”

7. Main results

Although body weight and waist circumference were significantly decreased in both arms (P=0.000), no inter-arm difference in the body composition parameters or metabolic biomarkers were found. Correlation analysis revealed that change in body composition was positively correlated with endotoxin level (γ=0.441, P<0.05 for body weight; γ=0.350, P<0.05 for fat mass) and lactic acid bacteria count (γ=0.425, P<0.05 for body weight; γ=0.407, P<0.05 for BMI). The body composition parameters, waist circumference and total cholesterol level were positively correlated with Gram negative bacteria count (γ=0.359 and γ=0.393, respectively; P<0.05 for both) and *Bifidobacterium breve* count was negatively correlated with endotoxin level (γ=−0.350, P<0.05).

8. Conclusions

Correlation between gut microbiota and change in body composition shows that probiotics affect energy metabolism in obese subjects. Correlation between endotoxin level and body weight decrease suggests that probiotics play a role in preventing the growth of endotoxin-producing bacteria in gut microbiota that promote obesity-associated dysbiosis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor’s comments

This DB-RCT was conducted in the Republic of Korea and evaluated the effects of co-administration of bofutsushosan and probiotics on obesity. This study was a registered clinical trial of the Korean National Institute of Health (NIH) and seems to be a well-designed study. Although body weight was decreased in both arms, the body weight decrease was not significantly different between arms. Therefore, the efficacy of adding bofutsushosan to probiotics remains unknown. In the article, the authors focused mainly on the results of correlation analyses rather than the effectiveness of probiotics. Research questions posed at the time of the study’s design seem to remain unanswered. The significance and effects of co-administration of bofutsushosan were poorly described. More explanation is needed. Further development of this research is anticipated.

12. Abstractor and date

Tsuruoka K, 31 March 2017.