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Original Research

Aster spathulifolius Maxim extract reduces body weight and fat mass in obese humans

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ABSTRACT

Aster spathulifolius Maxim (AS), a perennial herb of the genus *Aster* within the family Asteraceae, induced weight loss in a rat model of diet-induced obesity. We hypothesized that AS could also reduce body weight in obese humans. Therefore, we performed a randomized, double-blind, placebo-controlled clinical trial in Korea to evaluate the effect of AS extract (ASE) on body weight and fat mass and its safety in obese humans. Forty-four obese participants (body mass index [BMI], 25-30 kg/m^2) aged ≥20 years were randomly assigned to the placebo or ASE group (700 mg/d of ASE) and were instructed to take a once-daily pill for 12 weeks. Weight, BMI, waist circumference, fat mass (measured using bioimpedance, dual-energy X-ray absorptiometry, and computed tomography), and laboratory tests were assessed at baseline and at 12 weeks. Body weight significantly decreased after 12 weeks of treatment in the ASE group (placebo vs ASE: −0.08 ± 2.11 kg vs −3.30 ± 3.15 kg, $P < .05$), and so did body fat mass (placebo vs ASE; bioimpedance method: −0.51 ± 1.89 kg vs −2.38 ± 2.30 kg, $P < .05$; dual-energy X-ray absorptiometry: 0.38 ± 1.59 kg vs −2.26 ± 2.37 kg, $P < .05$). Changes in lipid profiles, fasting plasma glucose, and hemoglobin A1c did not differ between the 2 groups. No drug-related adverse events were observed during the study. In conclusion, ASE significantly decreases body weight and fat mass in obese humans, suggesting that ASE may be a potential therapeutic candidate for reducing obesity.

Abbreviations: ALT, alanine aminotransferase; AMPK, adenosine monophosphate–activated protein kinase; Apo-B, apolipoprotein B; ASE, *Aster spathulifolius* Maxim extract; AST, aspartate aminotransferase; BMI, body mass index; CGA, chlorogenic acid; CT, computed tomography; DEXA, dual-energy X-ray absorptiometry; DM, diabetes mellitus; FPG, fasting plasma glucose; HbA1c, hemoglobin A1c; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NS, not significant; PPAR, peroxisome proliferators-activated receptor; TG, triglycerides; UCP, uncoupling protein.

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1. Introduction

Obesity is a major health issue, and its global prevalence has increased consistently during the past several decades [1]. Worldwide obesity has more than doubled since 1980. In 2014, more than 1.9 billion adults, 18 years and older, were overweight, of whom 600 million were obese [2]. Obesity is determined using the body mass index (BMI). In Asian populations, including the Korean population, a BMI of 23 to 24.9 kg/m^2 is defined as overweight; and a BMI ≥25 kg/m^2, as obesity [3,4]. According to data from the Korea National Health and Nutrition Examination Survey, the prevalence of obesity in Korea has increased during the past decade: 32.8% of the Korean adults are obese, of whom 36.1% are men and 29.7% are women [3,5]. Obesity increases the risk of cardiovascular disease, type 2 diabetes mellitus (DM), dyslipidemia, metabolic syndrome, hypertension, and several cancers [6,7]. Consequently, it increases morbidity and mortality [8,9]. Therefore, the early diagnosis and optimal management of obesity are essential in reducing complications.

Diverse approaches to weight loss exist, including lifestyle modification (eg, energy restriction and increased physical activity), pharmacotherapy, and bariatric surgery. Drug therapy is recommended in addition to lifestyle interventions for obese and overweight individuals with more than 1 comorbid disease (DM, hypertension, dyslipidemia, or sleep apnea) [3]. However, less than 5% of the individuals attempting to lose weight do so through the use of prescription drugs [10]. This might be due to concerns about drug-related adverse events or medication cost. Although several dietary supplements, such as herbal products or functional foods, for reducing body weight have been developed and studied, their effects are not convincing [11,12].

Aster spathulifolius Maxim (AS) is a perennial herb of the genus *Aster*, within the family Asteraceae [13]. It is distributed along the eastern and southern coasts of South Korea, southwestern Japan, and China [14]. Aerial parts of AS are traditionally used as edible vegetables in Korea [13,14]. Previous studies have evaluated the effects of AS. For example, AS extract (ASE) possesses antiviral activity against the influenza A/PR/8/34 virus [15] and cytotoxicity against human tumor cell lines [16,17]. In addition, in vivo assays have shown that ASE has antidiabetic effects [18]. In a preclinical experiment using Sprague-Dawley rats fed a high-fat diet, ASE reduced fat mass and improved lipid profiles, thereby causing weight loss [19]. Therefore, we hypothesized that ASE could reduce body weight and performed the first clinical trial to evaluate the efficacy and safety of ASE in obese humans.

2. Methods and materials

2.1. Study design

This study was a 12-week, randomized, double-blind, placebo-controlled clinical trial conducted from October 2013 to October 2014 in Kyung Hee University Hospital at Gangdong, Seoul, Korea. Obese (BMI = 25-30 kg/m^2), nondiabetic individuals aged ≥20 years could participate in this study. The exclusion criteria were as follows: (1) high aspartate and alanine aminotransferases levels (AST or ALT >3 times the upper limit of normal); (2) serum creatinine >1.5 mg/dL; (3) thyroid-stimulating hormone ≥10 mIU/L; (4) individuals who had taken medication for treating obesity within the previous 3 months; (5) individuals who had taken a glucocorticoid within the previous 3 months; (6) individuals with serious illness (eg, cancer, heart disease, and psychiatric disease); and (7) drug abusers. All participants were assigned randomly to the placebo group, or the ASE group, which received 700 mg of ASE. The compositions of placebo and ASE capsule are shown in Table 1. All participants were instructed to take a pill once daily with drinking water within 30 minutes after breakfast for 12 weeks. The Institutional Review Board approval was obtained before the start of the trial, and all participants provided written informed consent.

2.2. Preparation of ASE

Aster spathulifolius Maxim was collected from the coasts of Ulleung Island in Republic of Korea. It was authenticated by a manager at Ulleung-gun Agriculture Technology Center (Ulleung-gun, Republic of Korea). Dried leaves of AS were ground to fine powder. The ground sample was refluxed 3 times with 50% ethanol at 60°C for 4 hours. After filtering, the extract was evaporated using a rotary evaporator (Eyela, Japan) followed by spray-drying (yield, 27.1%). The components of the thus-obtained ASE had been analyzed previously [20]. ASE was developed and provided by Newtree Co, Ltd (Sungnam, Republic of Korea). We determined the daily dose in our clinical trial based on in vivo animal study data [19]. The concentration of ASE that caused weight loss in this animal study was 125 mg/kg body weight for rats (0.086 mg/cm^2 of body surface areas). The ratio of the body surface area in the tested species (rats) to that of humans is 5.45. The human equivalent dose can be calculated directly from the animal dose by multiplying by the factor 1/10-1/100; the ASE dose for a 60 kg human being is, thus, 0.085-0.85 g. We decided on a dose of 700 mg ASE to facilitate dosing in capsule form.

2.3. Efficacy evaluation

The primary study end points were changes in weight, BMI, and fat mass after 12 weeks of treatment. Weight, height, BMI,

Table 1 – Compositions of test supplements

Component	% Weight	
	Placebo	ASE
ASE	0	38.8
Cellulose	90.9	53
Silicon dioxide	2	2
Magnesium stearate	1	1
Hydroxypropylmethyl cellulose	4.81	3.91
Titanium dioxide	0.69	0.69
Glycerin esters of fatty acids	0.4	0.4
Cacao color	0.2	0.2
Total (%)	100.0	100.0