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Beneficial effects of whey protein preloads on some cardiovascular diseases risk factors of overweight and obese men are stronger than soy protein preloads – A randomized clinical trial

Atefeh Tahavorgar [a], Mohammadreza Vafa [b, c, *], Farzad Shidfar [b], Mahmoodreza Gohari [d], Iraj Heydari [c]

[a] School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Enqelab Square, Tehran, Iran
[b] Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Hemaat Highway, 1449614535, Tehran, Iran
[c] Endocrine Research Center (Firouzgar), Institute of Endocrinology and Metabolism, Iran University of Medical Sciences, Hemaat Highway, Tehran, Iran
[d] Department of Statistics, Iran University of Medical Science, Tehran, Iran

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ABSTRACT

Background: The hypothesis that long term supplemental preloads of whey protein concentrate (WPC) and soy protein isolate (SPI) 30 min before the largest meal, will improve blood pressure (BP), fasting blood sugar (FBS) and lipid profile of overweight and obese men in their in free living condition was tested.

Methods: Forty - five men of 52, BMI = 25–40 kg/m^2, after random allocation in WPC (n = 26) or SPI (n = 19) groups, drank 65 gr WPC or 60 gr SPI dissolved in 500 ml water 30 min before their ad libitum lunch for 12 weeks. Lipid profile and FBS were assessed before and after the study. Systolic and diastolic BP were measured before and after the study and every two weeks.

Results: After 12 weeks, mean changes between the groups were significant for SBP ($p < 0.02$), DBP ($p = 0.001$), apo A-I, apo B ($p < 0.001$), LDL ($p = 0.015$), HDL ($p = 0.017$). Within group mean changes of WPC were significant for reduction of DBP, FBS, apo B, VLDL, LDL, TG ($p < 0.001$), SBP, TC ($p = 0.001$), and for increase of apo A-I ($p < 0.001$) and HDL ($p = 0.001$) relative to baseline. In SPI group, mean changes were significant relative to baseline for decrease of SBP ($p < 0.02$), DBP ($p = 0.001$), apo B ($p < 0.001$), LDL ($p = 0.015$) and for increase of apo A-I ($p < 0.001$) and HDL ($p = 0.017$).

Conclusion: According to this study, WPC preloads at 30 min before ad libitum main meal, exert stronger beneficial effects than SPI preloads on BP, FBS and lipid profile of free living overweight and obese men after 12 weeks.

Trial registration: Iranian Registry of Clinical Trials: IRCT201109062365N3.

1. Introduction

A leading cause of cardiovascular diseases is the accelerating increase in the prevalence of obesity with its related complications of hypertension, dyslipidemia, diabetes and atherosclerotic vascular disease [1]. Two major goals of dietary recommendations are to lower blood pressure (BP) and improve serum lipids, 2 of the primary determinants of CVD risk [2]. In this regard, life style modifications such as losing weight, increasing physical activity, reducing the consumption of salt and saturated and trans fatty acids and increasing the consumption of fruits and vegetables have been consistently shown to improve BP, blood lipids and blood glucose [3,4]. On the other hand, limited studies have shown beneficial effects of high protein diets on BP, blood lipids [5–7] and glucose [8]. Studies show that the quality and quantity of dietary protein affect the plasma cholesterol levels [9]. Interestingly, the inverse association between dairy consumption and metabolic disorders [10] may be contributed to dairy-derived special components like calcium and other minerals, whey or casein proteins [11]. Current evidence demonstrates that ACE inhibiting peptides of

* Corresponding author. Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Hemaat Highway, 1449614535, Tehran, Iran.
E-mail addresses: athvgr_ndt@yahoo.com (A. Tahavorgar), rezavafa@yahoo.com (M. Vafa), f-shidfar@tums.ac.ir (F. Shidfar), mgohari@tums.ac.ir (M. Gohari), Irajheydari@gmail.com (I. Heydari).

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List of abbreviation

ACE	angiotensin converting enzyme
BCAA	branched-chain amino acids
WPC	whey protein concentrate
SPI	soy protein isolate
FBS	fasting blood sugar
TC	total cholesterol,
TG	trilglyceride
LDL	low density lipoprotein
HDL	low density lipoprotein
VLDL	very low density lipoprotein
Apo A-I	apoliprotein A-I
Apo B	apoliprotein B
BMI	body mass index
IPAQ	international physical activity questionnaire
SBP	systolic blood pressure
DBP	diastolic blood pressure
NASH	nonalcoholic steatohepatitis

whey protein, the by product of cheese producing, can be effective in decreasing hypertension [12]. On the other hand, beneficial effects of whey protein on lipid profile are contributed to inhibiting the expression of genes involved in fatty acid and cholesterol absorption and synthesis [13]. Furthermore, high concentrations of BCAAs (leucine, isoleucine and valine) in whey protein have beneficial effects on blood glucose [14]. Moreover, considering the fact that soy protein is rich in genistein, daidzein and glycitein isoflavones [15], it can reduce hypertension [16] and blood glucose [17]. Additionally, two main protein components, β-conglycinin and glycinin also have cholesterol lowering effects [18]. Despite numerous studies comparing effects of high protein diets from mixed sources, studies on the effects of long term supplemental WPC and SPI preloads before ad libitum food intake on metabolic risk factors in overweight and obese individuals without changing physical activity and dietary intake are scarce and similar studies have revealed controversial results [19–23]. According to similar interventions, whey protein either in concentrated or isolated form is mostly compared with carbohydrate as a control group [24,25] which masks the effects of high protein diets on metabolic factors as a confounding factor, thus it is not obvious whether the results are related to the high protein diet or to the specific characteristics of the protein type for instance whey or soy protein. Indeed, studies evaluating effects of soy protein intake and whey protein on apo A-I need more investigations and also understanding which protein sources are associated with lower CVD risk factors is important because substituting one protein for another may help individuals benefit from high protein diets.

Thus, the objective of the present study was to test the hypothesis that preloading free living overweight and obese men with supplemental WPC and SPI at 30 min before their ad libitum lunch meals (the largest meal of obese men) can decrease BP, FBS, TC, TG, LDL, HDL, VLDL, apo A-I and B.

2. Methods and materials

2.1. Study population and design

Volunteer employees of power plant generation of Karaj city were recruited to participate in the study by monthly bulletin. The study population was calculated 46 according to apo B which was increased to 52 to prevent 12% possible participant dropouts. A total of 7 visits were included: one prior to the study for screening and baseline data collection and also 1 visit at the end of weeks 2, 4, 6, 8, 10 and 12 for completing questionnaires of 24-h dietary recalls, anthropometry and body composition measurements. Senior researcher completed all questionnaires to minimize misreporting. Of 85 volunteers, 52 men, age 30–65 yr, BMI = 25–40 kg/m^2 were recruited according to the following inclusion criteria: no cigarette smoking and alcohol consumption, no taking medication and supplements, no high amounts of caffeine consumption (>250–300 mg/d), no history of diseases or clinical problems increasing oxidative stress (injuries or burns), no allergy to soy/cow's milk and no severe weight changes within 3 last months (according to medical history of employees' records and their physical examination by the physician of the power plant). Exclusion criteria: changes in physical activities (PA), diets and also a compliance of 70% or lower for consumption of treatment beverages. Percent of consumed to distributed sachets were used to assess the compliance. At visit 1, eligible participants were randomly assigned to groups WPC or SPI (26 in each) using a convenience allocation. Individuals were instructed to deliver empty sachets in exchange for full ones at visits 2 to 12 for calculating compliance. All participants had ad libitum access to calorie and were asked to maintain their usual dietary intake and physical activity levels during the study. They were instructed to dissolve one sachet in 500 ml water and drink it 30 min before lunch meal (as the largest Iranian meal) every day. Aside from assessing compliance at biweekly visits, participants were observed directly at random visits at lunchtime in their workplaces to ensure the supplements were taken appropriately. They gave their written informed consent before participating in the study. The present study was conducted according to consolidated standards of reporting trials (CONSORT) guidelines [26] and has been registered in the Iranian Registry Clinical Trials (IRCT201109062365N3).

The Ethics Committee of Tehran University of Medical Sciences approved this study (Ethics Committee: 2011-06-17-13475-43649).

2.2. Treatment beverages

Preload proteins were WPC 80% (DMV, Netherlands) and SPI 90% (Red Crown, China) with almost similar color and texture. Sachets contained 67.5 g WPC and 60 g SPI (54 g effective compound as a protein/sachet). Calorie content of WPC and SPI sachets were 261.8 Kcal and 216 Kcal respectively. They were all closely matched for taste by strawberry flavor and sucralose (Vita Sweet, China) (0.2 gr and 0.1 gr in each sachet respectively), as a no-energy sweetener because sucralose is not metabolized in the body and has no effect on blood glucose or insulin secretion [27]. After packing in 4368 similar sachets for 84 days, they were numbered 1–84. The numbers were randomly divided into groups A and B (SPI and WPC respectively) and kept by research executive director until study complement. Hence, all groups were blinded for both participants and senior researcher. Protein concentration of treatment beverages was 13% for WPC and 12% for SPI.

2.3. Dietary intake and physical activity assessment

All 24-h dietary recalls were completed (1 weekday and 1 weekend day) before the study and at every 2 weeks (2, 4, 6, 8 and 12) [28]. Calorie and nutrient compositions were calculated using Nutritionist 4 software. PA was recorded by international physical activity questionnaire (IPAQ) and recorded as metabolic equivalent/wk (MET-Minute/Wk) [29] before the study, at the end of months 1, 2 and 3. MET values of 3.3, 4 and 8 were respectively considered for walking, moderate and vigorous intensity activities.