Effect of different protein diets on weight loss, inflammatory markers, and cardiometabolic risk factors in obese women

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Background: Reducing and maintaining body weight has become more important than ever as obesity is becoming increasingly common worldwide. This study was aimed to investigate the effects of diets with different protein contents administered to obese women on anthropometric measurements, inflammatory markers, and cardiometabolic risk factors.

Materials and Methods: This randomized controlled trial was conducted with sixty volunteering obese women aged between 20 and 45 years. The subjects were divided into two groups in equal numbers. The high-protein (HP) group (n = 30) was administered an iso-caloric HP diet (25% protein, 30% fat, and 45% carbohydrate), and the control group (n = 30) an isocaloric low-protein diet (15% protein, 30% fat, and 55% carbohydrate), and both groups were followed up for 8 weeks. The subjects’ descriptive data, anthropometric measurements, homeostatic model assessment-insulin resistance (HOMA-IR), lipid profiles, and high-sensitive C-reactive protein (hs-CRP), tumor necrosis factor-alpha (TNF-α), and interleukin-6 (IL-6) levels were analyzed.

Results: There was no significant difference at baseline (except for low-density lipoprotein cholesterol [LDL-C]), and end-of-study (except for IL-6, systolic blood pressure [SBP], and diastolic blood pressure) values of parameters between the two groups; after adjusted for baseline measurements, a significant difference was observed between the groups for body weight, body mass index, waist circumference, HOMA-IR, LDL-C, hs-CRP, TNF-α, IL-6, and SBP (P = 0.004, P = 0.001, P = 0.003, P = 0.029, P = 0.004, P = 0.016, P = 0.004, P = 0.010, and P = 0.000, respectively) and were greater in the HP group than in the control group (P < 0.05).

Conclusion: The HP diet was effective on improvement in HOMA-IR, SBP, LDL-C, hs-CRP, TNF-α, IL-6, and resulted in body weight loss.

Key words: Cardiometabolic risk factors, dietary proteins, inflammation, obesity, weight loss

INTRODUCTION

Urbanization, economic developments, and globalization have led to fast changes in lifestyles and diets with an impact on the nutrition status of people. This caused the emergence of major health and eating problems such as obesity. [1]

Insulin resistance, noninsulin-dependent diabetes mellitus, hypertension, dyslipidemia, coronary heart disease, gallbladder diseases, osteoarthritis, sleep apnea, respiratory problems, increased pro-inflammatory marker levels, and many types of cancer have all been reported to be associated with obesity. [2] Obesity-related adipocyte hypertrophy and metabolic endotoxemia resulting from weight gain attract macrophage infiltration into adipose tissue, with subsequent chronic inflammation such as C-reactive protein and secretion of pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6). This effect exacerbates chronic systemic inflammation, insulin...
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(HP) diets in contrast to weight loss and weight maintenance is associated with their ability to stimulate the satiety center, increased satiety, postprandial thermogenesis, fat-free mass (FFM), and total energy expenditure (TEE), resulting in less food intake. Recent studies have shown that energy-restricted HP diets induce remarkable weight loss and waist circumference (WC), resulting in a greater improvement of cardiometabolic parameters such as glycemic control, insulin resistance, lipid profile (total cholesterol, low-density lipoprotein cholesterol [LDL-C], triglyceride [TG]), hypertension, and high-sensitivity CRP (hs-CRP) and pro-inflammatory markers (TNF-α, IL-6) compared to carbohydrate-dense hypocaloric diets. HP diets showed suggestive and/ or weak evidence of a reduction in weight and body mass index (BMI) but contrasting evidence for lipid, glycemic, and blood pressure parameters, suggesting potential risks of unfavorable effects.[17]

The amount of protein that enhances weight loss is controversial; nonetheless, diets with a higher proportion of protein and fewer carbohydrates have proven to be effective for weight loss in obese adults and lead to improved cardiometabolic parameters.[18] There is no consensus on what a HP diet is. Both the World Health Organization (WHO) and the Food and Nutrition Board of the Institute of Medicine (National Academy of Sciences, United States), which issues the Recommended Dietary Allowance, established that the dietary reference intake of protein is 0.8 g/kg per day in adults. According to Dietary Reference Intake, the proportion of daily energy consumed from protein should approximately 10%–35% in adults,[19,20]

This study aimed to investigate the effects of diets with different protein contents administered to obese women on anthropometric measurements, inflammatory markers, and cardiometabolic risk factors.

MATERIALS AND METHODS

Subjects and study design

This randomized controlled trial was conducted with female volunteers aged between 20 and 45 years who presented to the Endocrine or Internal Medicine Outpatient Clinic of Erzincan Mengüce Gazi Training and Research Hospital and were afterward referred to the Diet Outpatient Clinic. Participants who voluntarily agreed to contribute to this study were asked to sign a written consent form in accordance with the Helsinki Declaration. Ethical approval for the study was obtained from the Clinically Ethics Board of Erzincan University, Erzincan, Turkey (Project No: 44495147-050.01.04-E.40589).

The study included women who had a BMI between 30 and 35 kg/m² (obese) and had a sedentary lifestyle or a very low level of physical activity (physical activity value: 1.40–1.69). Those who were pregnant or breastfeeding, who had diabetes, a liver or kidney disease, active or past malignancy, hypothyroidism or hyperthyroidism, acute or chronic inflammatory disease, or severe psychiatric disease, who were receiving steroid therapy, who followed a diet within the past 3 months and lost more than 5% of their weight, who were engaged in heavy physical activity, and who received regular vitamin-mineral supplements within the past 3 months were excluded.

According to the study of Azadbakht et al.,[17] the sample size was calculated using the NCSS PASS 2008 software to be at least 52 persons, with approximately 26 participants in each group considering the following parameters; Type 1 error (α) of 0.05 (95% confidence), Type 2 error (β) of 0.20 (80% power), as well as 20% dropout rate (the research involves the intervention phase, individuals are not able to follow the diet, pregnancy). The group that was given a HP diet comprised the HP group, and the group that was given a control diet comprised the control group. Among the participants meeting the inclusion criteria, 100 women were randomly selected for simple randomization (tossing a coin) to one of two diets. However, the study was completed with sixty women, thirty in each group. Care was taken to include subjects with similar ages and BMIs in both groups. The subjects who met the inclusion criteria were administered a diet therapy for 8 weeks and were followed up every week during the 1st month and every other week during the second month.

Data collection

The descriptive characteristics of the participants were recorded in data gathering form.

Biochemical parameters and blood pressure

Blood samples were taken for routine controls for those who presented to the Endocrine or Internal Medicine outpatient clinic (fasting blood glucose, fasting insulin, lipid profile (total cholesterol, TG, LDL-C, high-density lipoprotein-cholesterol [HDL-C]), and some biochemical parameters to be used for the study such as hs-CRP, TNF-α, and IL-6 were analyzed at the baseline and the end of week 8 at the Biochemistry Laboratory of Erzincan
Mengücek Gazi Training and Research Hospital. Insulin resistance was evaluated using the homeostatic model assessment-insulin resistance (HOMA-IR) method was determined using the formula: [(fasting plasma glucose × fasting blood insulin)/405]. HOMA-IR ≥2.5 is accepted as insulin resistance.\[^{[21]}\] After 5 min of rest, the physician measured participants’ blood pressure three times in the sitting position and recorded the average of the three measurements.

### Planning of the diet therapy intended for the subjects

The basal metabolic rate (BMR) of the subjects was calculated based on their adjusted weight ([current weight – ideal weight] × 0.25 + ideal weight).\[^{[22]}\] The BMR equation prepared by the Experts Committee of the United Nations Food and Agriculture Organization, WHO, and United Nations University for women was used.\[^{[23]}\] A 3-day physical activity recording form was completed for the subjects. The total energy requirement was found by multiplying the energy expended for each activity, the activity-specific physical activity rate, the duration of the activity (minutes), and the BMR per hour. Diet schedules were planned according to the daily energy requirements by a dietician. The HP group was administered an isocaloric HP diet based on their daily energy requirements (25% protein, 30% fat, and 45% carbohydrate), and the control group an iso-caloric control diet (15% protein, 30% fat, and 55% carbohydrate).\[^{[7,19,20]}\] and both groups were followed up for 8 weeks. The ratio of animal protein to plant-based protein was 1:1 in both the HP and control group diets. Animal protein was obtained from meat and dairy products (low-fat or no-fat). A dietician provided participants with individual regimen consultation and instructions on dietary requirements at the start, once per week in the 1st month, and once in 15 days in the 2nd month throughout the study. Participants completed 3-day consecutive food records and physical activity records on the same days before each visit. Energy and macronutrient intake was analyzed by a computerized nutrition system (BeBiS) programme.

### Anthropometric measurements

Some of the anthropometric measurements of the subjects (height, weight, and WC) were performed at the baseline and the end of week 8. Their BMIs were calculated. Bodyweight was measured in light clothing and with no shoes using a portable scale. Height was measured with a wall-mounted stadiometer with an accuracy of 0.1 cm. BMI was calculated as weight (kg)/height (m\(^2\)). The WC was measured with a tape measure using the line between the lower costal border and the iliac crest as reference points.\[^{[22]}\] All measurements were obtained as previously described by trained intern dietitians. According to the WHO guidelines, obesity was defined as BMI ≥30 kg/m\(^2\).

### Statistical analysis

All data obtained from the study were analyzed using SPSS 21.0 (SPSS version 21.0, Chicago, USA). The data were expressed as mean ± standard deviation for numeric variables. The normality of the distribution of numeric variables was evaluated using the Kolmogorov–Smirnov test. Mann–Whitney U-test was used for group comparisons. In the univariate analysis, to adjust for baseline measurements, analysis of covariance was carried out. The level of significance for the statistical tests was set at α=0.05.

### RESULTS

This study was conducted with sixty women, thirty in the study group that received a HP diet, and another thirty in the control group that received a control diet. The flowchart of the study is shown in Figure 1. The baseline demographic and clinical characteristics of participants are shown in Table 1. The mean age of the women was 33.2 ± 6.91 years (HP group: 32.3 ± 7.45 and control group: 34.1 ± 6.49).

A comparison of the mean anthropometric measurements of the subjects is shown in Table 2. The amount of bodyweight loss was 7.1% in the HP group and 5.3% in the control group. There was no significant difference at baseline, and end-of-study values of anthropometric measurements between the two groups; however, in the univariate analysis, after endpoint values adjusted for baseline measurements,
SBP were significantly greater in the HP group than in the control group (P = 0.024, P = 0.001, P = 0.030, P = 0.004, P = 0.028, and P = 0.000, respectively) [Table 3]. There were no differences between the baseline and end-of-study values of lipid profile (total cholesterol, TG, and HDL-C) and DBP (P > 0.05).

**DISCUSSION**

This study evaluated the effects of the HP and control diets administered to women on some anthropometric measurements, inflammatory markers, and cardiometabolic risk factors.

A low-energy diet was administered to 773 overweight and obese subjects for 8 weeks. More than 8% of weight loss was achieved in 420 subjects who were administered HP (23%–28%) and low-protein (10%–15%) diets for 6 months. The group that had a HP diet was observed to have more weight loss.\footnote{Mann-Whitney U test (P<0.05), P value 1=The significance of the baseline values of the study between the groups; P value 2=The significance of the end-of-study values between the groups; Adjusted P value 2=Adjusted for baseline measurements; P 3=The significance of the difference between the diet. BMI=Body mass index; WC=Waist circumference}
Similar to the above study, Yoldaş et al.[24] found that their study group receiving a diet with 25% protein had more bodyweight loss and reduction in their BMI at the end of 6 weeks compared to the women in the control group.

Sixty overweight/obese women aged 20 to 65 who had a HP diet (25% protein, 45% carbohydrate, and 30% fat) and an energy-restricted control diet (15% protein, 55% carbohydrate, and 30% fat) were monitored for 3 months. Weight loss and WC reduction were observed in the women who had a HP diet.[7]

In the present study, the amount of body weight loss was 7.1% in the HP group and 5.3% in the control group. Similar to other studies,[7,11,24] this study also revealed that there were more decreases in body weight, BMI, and WC in the HP diet group than in the control group.

HP diets are reported to improve blood parameters through weight loss. Studies have argued that HP diets may reduce cardiovascular disease factors by positively affecting insulin sensitivity and serum lipid profile and prevent loss of lean body mass during bodyweight loss, resulting in a positive impact on insulin sensitivity.[25,26] In the present study, there was a higher decrease in the HOMA-IR values of the high-diet group compared to the control group. This result shows that HP diets protect body muscle mass and improve insulin sensitivity while losing weight.

According to a meta-analysis where HP diets were compared to low-protein diets in periods between 28 days and 12 months, HP diets had positive effects on HDL-C, TG, and blood pressure, which are obesity markers and cardiovascular risk factors.[9] In this study, HP and control group subjects showed a decrease in total plasma cholesterol, TG, and LDL-C levels at the end of week 8. Compared to the control diet, the HP diet resulted in a significant decrease in the LDL-cholesterol values ($P < 0.05$).

A low-calorie diet was administered to 773 overweight and obese subjects for 8 weeks. More than 8% of weight loss was achieved in 420 subjects who were administered high (23%–28%) and low-protein (10%–15%) diets for 6 months. Positive results were obtained in blood pressure and weight loss in the HP diet group.[11] In a study by Engberink et al.[12] there was a BP reduction after weight loss was better maintained when the intake of protein was increased at the expense of carbohydrates. In our study, similar to the results of other studies,[8,11] there was a decrease in the SBP and DBP values in both the HP and control group subjects at the end of 8 weeks. Compared to the control group, a significantly more decrease was found in systolic blood pressure in the HP diet group ($P < 0.05$). This effect is partly mediated by weight loss.

In the present study, a decrease was seen in the serum hs-CRP, TNF-$\alpha$, and IL-6 values at the end of 8 weeks in both the HP and control groups. However, the decrease in the serum hs-CRP, TNF-$\alpha$, and IL-6 values was more significant in the HP diet group compared to the control group ($P < 0.05$). The results of this study are similar to those of the other studies.[8,10]

Sixty overweight/obese women aged 20–65 had a HP diet (25% protein, 45% carbohydrate, and 30% fat) and an energy-restricted control diet (15% protein, 55% carbohydrate, and 30% fat) for 3 months. Their hs-CRP, lipid profile, blood pressure, and anthropometric measurements were assessed. While weight loss and reduction in WC were seen with the HP diet, the hs-CRP, lipid profile, and blood pressure in the HP group were significantly lower than in the control group ($P < 0.05$).
pressure levels decreased with the energy-restricted diet regardless of the protein content.[7]

Ninety obese individuals with metabolic syndromes were administered a HP diet (protein, carbohydrate, and fat percentages: 30%, 40%, and 30%, respectively) and an energy-restricted control diet (protein, carbohydrate, and fat percentages: 15%, 55%, and 30%, respectively) for 2 months. Decreases were detected in the body weight and hs-CRP, IL-6, and TNF-α values with the HP diet.[9]

In another meta-analysis, 1063 subjects over 18 years of age were assessed. Compared to an energy-restricted standard diet, an isocaloric HP diet was shown to decrease body weight, fat mass, and TG levels and increase lean body mass and BMR. The long-term impacts of a HP diet on weight loss and cardiometabolic risk are not clear.[4] HP diets have shown suggestive and/or weak evidence of a reduction in weight and BMI but contrasting evidence for lipid, glycemic, and blood pressure parameters, suggesting potential risks of unfavorable effects.[17] Another study showed that there were no significant differences in weight loss and cardiometabolic risk factors when the overall group was examined, but the participants with more adherence rate in the high protein diet group lost significantly more weight than the adherent participants in the standard protein diet group.[27]

HP/low-carbohydrate diets administered without taking into account the type of carbohydrate or the source of protein have been linked to the risk of cardiovascular disease.[28]

Diets with moderate-to-HP contents (those containing animal and plant-based protein) are reported to have no negative effect on cardiovascular disease parameters.[29]

In a study by Speaker et al.,[30] it was shown that foods with soy-based protein could be added to an energy-restricted/HP diet effectively to improve body weight, body composition, and cardiometabolic health. Since the HP diet used in this study consisted of foods containing low-fat or semi-skimmed animal protein and plant-based protein, we think it may have a positive effect on cardiovascular disease-related risk factors.

This study had several limitations. First, it was a single-centered randomized controlled trial. Second, it included a small sample size. The small sample size could have limited the significance of weight loss enhance the ability of the diet and the clear presentation of statistical results. Furthermore, our study only involved women; so, the findings and conclusions reached here cannot be extrapolated to other populations, and further research would be needed for them. Future research should include larger multicenter studies on both women and men.

**CONCLUSION**

The HP diet was effective on improvement in HOMA-IR, SBP, LDL-C, hs-CRP, TNF-α, IL-6, and resulted in body weight loss a follow-up visit at 2 months. These effects are associated with their ability to stimulate the satiety center, increased satiety, postprandial thermogenesis, FFM, and TEE, resulting in less food intake. This study suggests that a HP diet may have a positive effect on the risk factors associated with cardiovascular diseases since it consists of foods containing vegetable protein and low- or semi-fat animal protein. The short- and long-term effects of HP diets on body weight and composition and weight gain following weight loss and their potential side effects (cardiovascular disease risk, elevated blood pressure, and blood lipids and gastrointestinal effects) are not clear. Further controlled interventional studies covering longer periods need to be carried out to assess the effects of these diets on body weight and composition and biochemical parameters. We also think that, instead of these types of diets that enable fast weight loss but involve possible long-term risks that cannot be explained yet, weight-loss strategies with an adequate and balanced nutrition program are more reliable in obesity treatment.

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**Conflicts of interest**

There are no conflicts of interest.

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