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Effects of a novel therapeutic diet on liver enzymes and coagulating factors in patients with non-alcoholic fatty liver disease: A parallel randomized trial

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ABSTRACT

Objective: There are several reports regarding the role of therapeutic diets for patients with non-alcoholic fatty liver disease (NAFLD). Therefore, the aim of this study was to determine the effects of a low-calorie, low-carbohydrate soy-containing diet on lipid profiles, liver enzymes, and coagulating factors in patients with NAFLD.

Method: This was a randomized parallel clinical trial involving 45 patients with NAFLD. The participants consumed three kinds of diets for 8 wk. Patients were randomly assigned to consume a low-calorie diet; a low-calorie, low-carbohydrate diet; or a low-calorie, low-carbohydrate soy-containing diet. Measurements were done according to the standard method.

Results: Changes in weight were not significantly different in the three groups. The low-calorie, low-carbohydrate soy-containing diet could reduce alanine aminotransferase (−15.2 ± 12.1 versus −6.8 ± 4.6 in the low-calorie, low-carbohydrate diet, and −6.4 ± 4.4 IU/L in the low-calorie diet; $P = 0.02$) and serum fibrinogen levels (−49.1 ± 60.1 versus −12.9 ± 8.1 and −17.4 ± 8.4 g/L, respectively; $P = 0.01$). Reductions in aspartate aminotransferase were significantly higher in the low-calorie, low-carbohydrate soy-containing group. Changes in lipid profiles did not differ significantly between the groups. The soy-containing diet did reduce malondialdehyde more than the other diets ($P = 0.01$).

Conclusion: A low-calorie, low-carbohydrate soy-containing diet could have beneficial effects on liver enzymes, malondialdehyde, and serum fibrinogen levels in patients with NAFLD.

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Introduction

Non-alcoholic fatty liver disease (NAFLD) is a chronic liver disease that is prevalent worldwide [1] and that also can be a presentation of insulin resistance [2]. Insulin resistance is associated with lipid serum abnormalities and liver dysfunction in some types of NAFLD [3]. Liver abnormalities may be one of the factors that can lead to an increase in coagulating factor such as factor VII and protein C levels. High levels of some hemostatic parameters, which increase the risk for thrombosis, often are associated with lipid abnormalities [4]. Recent data suggest that diet and exercise have beneficial effects on management of this disease [5,6]. Most previous diet therapy strategies for NAFLD were focused on low-fat diets as fat consumption; especially cholesterol and saturated fatty acids are particularly steatogenic [7–9]. Although in recent studies, low-carbohydrate diets were emphasized more [10,11], it appears that a low-carbohydrate diet has more beneficial effects on abnormalities in NAFLD via improvement in insulin resistance [10,11]. Because insulin resistance is the core of the problems in NAFLD, a low-carbohydrate diet may be the best choice for these patients. There are also several studies on the beneficial effects of low-calorie diets for

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patients with NAFLD [5–12]. Some reports demonstrated that calorie restriction per se is beneficial regardless of macronutrient composition [5]. However, we are not aware of any all-inclusive diet for NAFLD and to our knowledge, there is no study to assess the effects of a low-carbohydrate, low-calorie diet on this patient population.

In addition to therapeutic diets, some types of food, such as those that are rich sources of antioxidants, may help control the abnormalities found in this disease. Recently, soy products have been mentioned as an important part of a diet for management of NAFLD in an animal model. It has been reported that soy protein retards the progression of non-alcoholic steatohepatitis through improvement of insulin resistance and steatosis based on the results in an animal model [13]. One study revealed that soy isoflavone reduced the hepatic lipid deposition and increased antioxidant capacity; which may be related to inhibition of SREBP-1 c and activation of peroxisome proliferator-activated receptor α (PPARα)expression in liver [14]. Other studies in rat models and also a recent review confirmed the same results [15–17]. However, most studies regarding soy intake and NAFLD are conducted on rat models and few are done in humans. It is necessary to standardize dietary recommendations in an evidence-based manner for patients with NAFLD. Therefore, we hypothesized that a low-calorie and low-carbohydrate diet may be the best choice as a therapeutic diet and that adding soy products to this kind of diet may increase its beneficial role. Thus, this study was conducted to determine the effects of a low-calorie, low-carbohydrate soy-containing diet on liver enzymes, lipid profiles, and coagulating factors in patients with NAFLD.

Methods and participants

Participants

The sample size for this study was calculated based on the formula, $N = 2[(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times S^2]/d^2$ [18] where $\alpha = 0.05$ (type 1 error) and $\beta = 0.20$ (type 2 error). Aspartate aminotransferase (AST) was determined as main variable. Variance of AST was 2.2 [19] and difference in mean of this variable was 3.0. The formula estimated that 11 participants were required for each group. So, the power for detecting differences between the treatment conditions for various outcomes in the present study was 80%. Therefore, according to this formula, we needed 11 patients in each group to complete the trial (33 patients in total). We recruited 45 patients with NAFLD to compensate for any possible exclusion (15 patients in each group). All participants were attending the Gastrointestinal Research Center, Baghiatollah University, Tehran, Iran. They were asked to complete a written consent form. This study was conducted in Gastrointestinal Research Center, Baghiatollah University, Tehran, Iran during 2012. The inclusion criteria were stages 1 and 2 NAFLD, which was confirmed by sonography, and was associated with high levels of alanine aminotransferase (ALT) and AST (both enzymes > 30 in men and >20 in women). Before entering the patients in the study, we checked all other possible causes for increased liver enzyme status to exclude other possible reasons for increased levels of ALT and AST. Serum ferritin, total iron-binding capacity, and plasma iron levels were measured to detect possible hemochromatosis. Other tests for detecting viral hepatitis, Wilson's disease, and autoimmune disorders of the liver were also conducted. Exclusion criteria were pregnancy or lactating; allergy or intolerance to soy nut; the presence of thyroid disorders, gastrointestinal diseases, infectious diseases, or diabetes; and having undergone surgery in the preceding 6 mo. This study was approved by the research council and ethics committee of Food Security Research center and School of nutrition and Food Science, Isfahan University of Medical Sciences (research project no. 185190), Isfahan Iran. The field of study was conducted in Gastrointestinal Research Center, Baghiatollah University, Tehran, Iran and the data was collected there. The study was registered in the Iranian registry of clinical trials (ID no: IRCT201105282839 N2) and http://www.clinicaltrials.gov (ID no: NCT01419912). We followed the CONSORT statement in writing this clinical trial manuscript.

Patient flow diagram is shown in Figure 1. In the present study, 45 patients were assessed for the eligibility and all were eligible to enter the present study. After completing the written consent form, the participants were randomized to one of three groups. All the patients completed the follow-ups and their data were entered into the analysis. The primary outcomes were liver enzymes status and coagulating factors, as well as lipid profiles. The prevalence of NAFLD was considered the secondary outcome. Primary and secondary outcomes were measured at baseline and after the trial.

Study procedure

An 8-wk randomized parallel, clinical trial was conducted to compare the effects of three types of diets. Participants were randomly assigned to one of three groups in which sequentially numbered containers were used as a mechanism to implement the random allocation sequence. Allocation ratio in each group was 15 participants. Randomization was done by the dietitian in the study. We attempted to match all three groups for body mass index (BMI), sex, probable medications, and age. As this study was a dietary intervention, it was not blinded for the patients or the dietitian. However, laboratory staff and individuals who analyzed the data were blinded to the groups of interventions. Patients were asked to follow one of these three diets for 8 wk: A low-calorie diet; a low-calorie, low-carbohydrate diet; and a low-calorie, low-carbohydrate soy-containing diet. Participants were free-living during the study period and although we prescribed the diets, they prepared their own meals. Thus, only dietary prescription was given to them during the study. We recommended that all participants engage in moderate physical activity for 30 min a day. All data were collected at baseline and after the trial for each group. Participants were asked to record their physical activity and food intake for 1 d every 2 wk during the study. We asked patients to record their physical activity during a 24-h period and to mention all activities engaged in during the day, citing the duration of each activity. We calculated the duration of all the activities in a day. In individual sessions, we checked records and asked about questionable points. Physical activity was calculated as metabolic equivalent task hours per day (MET-h/d) spent on work, transportation, housework, and any other activities. We calculated the MET.h/d values of all activities to arrive at the value of physical activity in a day. Participants' complications from diet and their medications were monitored carefully. Biochemical and anthropometric measurements were done at baseline (before the start of the trial) and at the end of trial.

Anthropometric assessments

All patients were assessed for anthropometric measurements including waist, height, and body weight at baseline and at the end of trial. Heights in standing position and without shoes was recorded to the nearest 0.1 cm. Body weight was measured to the nearest 0.1 kg while participants were minimally clothed without shoes with digital scales. BMI was calculated as body weight (kg)/height^2 (m). Waist circumference was measured in the place where the waist was narrowest over light clothing.

Diet

All the participants in this study were overweight or obese as was demonstrated by the mean BMI (28.7 ± 2.6 kg/m^2). Because they were overweight or obese according to the research ethics, we conducted a beneficial treatment for all groups. Thus, we chose the low-calorie diet for all three groups and the low-calorie diet acted as the control in this study.

The study involved three kinds of diets:

1. The low-calorie diet (group 1) was 200 to 500 calories lower than the required calories for each participant. Calorie restriction was considered according to participant's BMI category. A 200-calorie reduction was considered for overweight individuals and up to a 500-calorie reduction for obese participants. Fifty-five percent of calories were supplied by carbohydrates, 15% by proteins, and 30% by fats.
2. The low-calorie, low-carbohydrate diet (group 2) was to the diet assigned to group 1 regarding calorie intake. Forty-five percent of the calories were supplied by carbohydrates, 35% by fats, and 20% by proteins. In addition to focusing on a low-calorie diet, this group also received a low-carbohydrate diet.
3. The low-calorie, low-carbohydrate soy-containing diet (group 3) was similar to groups 1 and 2 regarding calorie intake. The composition of the macronutrients was similar to the group 2 diet except in this diet 30 g of soy nut was incorporated instead of 30 g of red meat.

Calorie requirements for each patient were calculated individually based on the equation of Institute of Medicine Food and Nutrition Board [20]. Diets were individually tailored using an energy count system and an exchange list was given to each patient to suggest substitutions for particular food items and to calculate energy. The benefits of each diet were explained by the study dietitian.

Soy nut was provided in suitable amounts in a separated box with a small glass showing 30 g. A 1-d dietary record was completed by all participants every 2 wk to determine adherence to the prescribed diet and soy nut intake. Dietary intakes of all patients were controlled by a dietitian.

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