Original Article

Ardeh (*Sesamum indicum*) Could Improve Serum Triglycerides and Atherogenic Lipid Parameters in Type 2 Diabetic Patients: A Randomized Clinical Trial

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Abstract

Background: Data suggest that sesame seeds have properties beneficial to modulating lipid disorders and decreasing cardiovascular disease (CVD) risk factors. The aim of this study was to investigate the effects of Ardeh, paste of ground unhulled sesame seeds, on lipid profiles and atherogenic lipid parameters.

Methods: This randomized clinical trial included 41 patients with type 2 diabetes, who were randomly assigned to one of the two groups: group A (Ardeh 28 g/d, n = 21) and group B (control, n = 20). After an initial two-week washout period, the patients in group A, replaced a part of their usual breakfast with two tablespoon (tbsp) (~ 28 g) Ardeh, while group B patients continued the usual breakfast meal for six weeks; energy content of both breakfast meals was maintained in the same range. Anthropometric measures, blood pressure, serum levels of total cholesterol (TC), triglycerides (TG), LDL-C, HDL-C, and atherogenic index of plasma (AIP; log TG/HDL-C), TC/HDL-C ratio, and LDL/HDL-C ratio were determined at baseline and six weeks later.

Results: After six weeks, there were significant decreases in serum TG (15.3 mg/dL) and AIP (39 %) in group A. Moreover, slight decreases in serum TC, LDL-C, and other atherogenic lipid parameters and a mild increase in HDL-C also were observed during Ardeh supplementation. Anthropometric measures and blood pressure were unchanged during the study period in both groups.

Conclusion: Ardeh could have favorable effects in decreasing CVD risk factors in type 2 diabetics.

Keywords: Ardeh, lipid profiles, sesame seeds, type 2 diabetes

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Introduction

Sesame (*Sesamum indicum*) seeds are categorized as a unique healthy food because of their high level of mono- and polyunsaturated fatty acids, vitamin E, fiber, phytosterols, and other nutraceutical components such as bioactive lignans, sesamin, sesamol, episesamin, and sesamolin.[1,2] Sesame seeds have been traditionally used worldwide as an important ingredient in the Middle Eastern cuisine such as sesame oil, sesame bars, Halva and Ardeh,[3] and for their medicinal and physiologic effects of sesame has been considered over a long period. Studies have investigated the multiple beneficial functions of sesame including antiaging, anticancer, and antioxidative activity; antihypertensive effects; and modulation of lipid metabolism and lipid peroxidation. Their effects in enhancement of liver function, and immunoregulatory and antithrombosis properties were also investigated; properties which have made sesame seeds and their byproducts functional foods beneficial in the prevention and treatment of chronic disease and metabolic disorder.[3,4]

The well-suited characteristics and appropriate composition of fatty acids, particularly linoleic acid and high polyunsaturated/saturated fatty acid ratio, high level of lignans, fiber, and tocopherols in sesame seeds may support the hypothesis that sesame seeds and their products may have favorable effects on lipid profiles and in reducing the risk of coronary heart disease, and, in particular, in high-risk conditions such as diabetes. Limited data are available confirming these effects of sesame; however, animal models have reported that sesame lignans exhibit ameliorative effects on lipid profiles and lipid peroxidation, and improve serum lipoprotein metabolism, with a decrease in atherogenic apolipoprotein B and an increase in apolipoprotein A-1.[5–8] In humans, inconsistent results following administration of sesame or sesame oil on lipid profiles and cardiovascular risk markers were observed.[9–12]

In this study, we hypothesized that supplementation with Ardeh, an Iranian traditional food stuff produced from ground unhulled sesame seeds, could have favorable effects on lipid profiles and atherogenic lipid parameters in type 2 diabetic patients.

Materials and Methods

Patients and study design

This was a parallel, randomized, double-blind and controlled study. Type 2 diabetic patients, aged 18 – 60 years with a clinical diagnosis of type 2 diabetes (for at least one year), were recruited from the Iran Diabetes Society; they were excluded if they had severe impairment of cardiac, hepatic, or renal function, gestation or

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Table 1. Baseline characteristics of the participants[1]

Parameters	Baseline values	
	Ardeh *(n = 20)*	Control *(n = 16)*
Age, *y*	50 ± 10	52 ± 9
Sex, *M/F*	4/16	4/12
Duration of diabetes, *y*	7.6 ± 5.5	7.4 ± 4.4
Weight, *kg*	72.3 ± 9.6	74.8 ± 9.7
Body mass index, *kg/m²*	28.5 ± 3.1	29.9 ± 3.4
Waist circumference, *cm*	93 ± 6.9	98 ± 8.2
Systolic blood pressure, *mmHg*	116 ± 18	125 ± 15
Diastolic blood pressure, *mmHg*	78 ± 10	81 ± 8
Total cholesterol, *mg/dL*	200 ± 43	179 ± 47
Triglycerides, *mg/dL*	164 ± 89	151 ± 54
HDL-C, *mg/dL*	50 ± 16.6	48 ± 10
LDL-C, *mg/dL*	121 ± 50	100 ± 41
Total cholesterol/HDL-C ratio	5.29 ± 5.55	3.80 ± 1.09
LDL-C/ HDL-C ratio	2.94 ± 2.28	2.13 ± 0.88
Atherogenic index of plasma	0.49 ± 0.4	0.47 ± 0.22

[1]Data are mean ± SD (no significant differences were observed between the groups).

lactation, or if they used insulin injection or consumed antioxidant supplements. Forty-one patients, initially eligible, were included in the study. The subjects were randomly assigned to one of the two groups: group A (Ardeh 28 g/d, n = 21) and group B (control, n = 20). Random allocation of patients to treatment groups was performed by sequentially numbered containers. Randomization was performed by an assistant and group allocation was blinded for the investigator and participants.

Ethics approval for the trial was obtained from Ethical Committee of the Research Institute for Endocrine Sciences of the Shahid Beheshti University of Medical Sciences. This clinical trial, registered in the "Iranian Registry of Clinical Trials" at ULR: http://www.irct.ir, with the following identification: IRCT201105161640N4, was conducted between March and July 2011. The results were reported according to Consolidated Standards of Reporting Trials guidelines.[13]

Interventions

During an initial two-week washout period following recruitment, energy content of breakfast meal was adjusted for all patients within the range of 270 kcal, without any changes in regular breakfast pattern. The patients were advised to avoid intake of foods containing sesame seeds or sesame oils. After this period, the patients in group A, replaced a part of their usual breakfast with two tablespoon (tbsp) (~ 28 g) Ardeh, so that energy content of breakfast be maintained in the same range; in group B, the patients continued with the usual breakfast meal. Each patient in group A received two boxes (1200 g) of Ardeh (grounded unhulled sesame seeds without any additives) purchased from Oghab Halva Company (Tehran, Iran). The patients were recommended to maintain their regular lifestyle, including diet and physical activity throughout the study period. The patients were contacted every week to evaluate compliance to the intervention and to enquire regarding any possible side effects such as allergic reactions.

Measurements

To monitor dietary compliance and assess nutrient intakes, three-day dietary recalls, including two weekdays and one weekend day, were collected at baseline and again after six weeks from subjects. Anthropometric measurements including weight, height, and waist circumference were measured at baseline and six weeks later. Weight of the subjects was assessed with minimally clothed and without shoes, using a digital scale (to the nearest 100 g). Height of the subjects was assessed using a tape meter at the standing position without shoes (to the nearest 0.5 cm). Waist circumference of the subjects was assessed using a tape meter, at the umbilical level without any pressure to the body (to the nearest 0.1 cm). Body mass index (BMI) was calculated as follows: weight / square of the height (kg/m^2). Blood pressure of the subjects was measured using a standardized mercury sphygmomanometer, after a 15-min rest in the sitting position and on the right arm. For each patient two measurements of blood pressure were taken and the mean of the two measurements was recorded.

Biochemical analysis

At baseline and again six weeks after intervention, 12-hr fasting blood samples were collected into tubes containing 0.1 % EDTA and centrifuged at 4 °C and 500 g for 10 min to separate plasma. Fasting plasma glucose was measured by the enzymatic colorimetric method using a glucose oxidation kit (Pars Azmun Company, Tehran, Iran). Serum total cholesterol (TC) and triglycerides (TG) levels were measured by enzymatic colorimetric analysis with cholesterol esterase and cholesterol oxidase and glycerol phosphate oxidase, respectively (Pars Azmun Company, Tehran, Iran). High- density lipoprotein cholesterol (HDL-C) was measured by the immunoturbidimetry method after precipitation of apo B- containing lipoproteins with phosphotungstic acid (Pars Azmun Company, Tehran, Iran). LDL-C was calculated from serum TC, TG, and HDL-C, according to the Friedewald equation. Inter- and Intra -assay coefficient of variations of all assays were < 5 %. The cardiovascular risk factors parameters including atherogenic index of plasma (AIP; log TG/HDL), the ratio of TC/HDL, and LDL/HDL were calculated as, at baseline and six weeks after intervention.

Statistical methods

The sample size was designed to detect a 25 mg/dL difference among groups in TC with 95 % CI and 90 % power; sample size with regard to the possible loss of the samples was calculated as 20 patients in each group. Statistical analysis was performed with SPSS (version 16.0; SPSS, Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to test for a normal distribution. Differences between the two groups at baseline were tested with t-test. Six-week changes in lipid profiles and atherogenic lipid parameters were calculated and Student's paired t-test was used to compare baseline and six-week values in each group. Mean changes of the variables from baseline were calculated by [(six-week values- baseline values) / baseline values) × 100], and t-test was used to compare these changes between the two groups. To compare means of the variables after six weeks and obtain the main effect of treatment, the general linear model (ANCOVA) was used with six-week values as dependent variables, baseline values as covariates, and treatment group as a fixed factor. P-values < 0.05 were considered significant.

Results

Of forty-one randomized patients, 36 completed the study [group A, n = 20 and group B, n = 16] and were included in the analysis (Figure1). Subjects' demographics are shown in Table 1. The mean age of the participants was 50 ± 10 and 52 ± 9 years, and duration of diabetes was 7.6 ± 5.5 and 7.4 ± 4.4 years, in groups A and B, respectively. No significant differences between the groups were seen for age, sex, duration of diabetes, and other anthropometrics and clinical measurements between the patients in the two groups at baseline. All of the patients were treated with oral anti-diabetic agents including metformin or glibenclamide or combination of these; the prevalence of the patients who were treated with hypolipidemic or hypotensive drugs in both groups was similar.

A regular breakfast meal for most patients, before the study, was bread and cheese; this pattern changed to bread and Ardeh for the intervention group, and remained unchanged for controls during the study. Both breakfast patterns had similar energy content ~ 270 kcal. Nutritional composition of Ardeh is presented in Table 2. The content of nutrients in both breakfast patterns is shown in Table 3. As compared to the control pattern, Ardeh consumption increased fat (total fat, monounsaturated fat, and polyunsaturated fat) and fiber, and decreased saturated fat content of breakfast meal in the group A.

Table 2. Nutritional composition of Ardeh

Parameters	**Ardeh** ***(2 tbsp ~ 28 g)***
Energy, *kcal*	172
Carbohydrate, *g*	5.1
Protein, *g*	5.07
Total fat, *g*	16
Saturated fat, *g*	2.24
Monounsaturated fat, *g*	6.04
Polyunsaturated fat, *g*	7.01
Dietary fiber, *g*	2.6

Based on the patient reports, lifestyle and medication status remained unchanged during the study period. Subject compliance was over 88 % for Ardeh (based on remaining weight of Ardeh at the end of treatment period) and 92 % for control groups, respectively. None of the patients in group A reported any adverse effects from consumption of Ardeh.

Mean differences of serum lipids and atherogenic lipid parameters compared with baseline values, are presented in Figure 2. After six weeks, there was a significant decrease in serum TG (15.3 mg/dL) and AIP (39 %) in the group A, compared to the control. A slight decrease in serum TC, LDL-C, and other atherogenic lipid parameters, and a mild increase in HDL-C also was observed during Ardeh supplementation. Anthropometric measures and blood pressure were unchanged throughout the study period in both groups (data are not shown).

Table 4 presents after treatment serum levels of lipids and atherogenic lipid parameters in the both groups; the analysis of covariance, adjusted for baseline values, showed that the consumption of Ardeh had significant effects in decreasing serum TG levels and AIP.

Discussion

The results of this clinical trial showed that replacement of regular breakfast meal with 28 g/d Ardeh, in type 2 diabetic patients for six weeks could have favorable effects on modulation of lipid profile disorders as main independent cardiovascular risk factors.

Increased serum TG and decreased HDL-C levels are the most common lipid disorders in type 2 diabetic patients which lead to development of CVD and increase disability and mortality in these patients;[14,15] in addition to drug treatment, dietary modification including use of functional foods in regular dietary pattern, may hence have beneficial effects for the prevention of cardiovascular diabetes complications.[16]

In this research, following the six-week consumption of Ardeh, serum TG decreased ~ 10 % and HDL-C tended to increase. The 39 % decrease in the AIP which was observed in the Ardeh group, compared to the control was another significant finding in the present study. AIP defined as logarithm of the TG/ HDL-C ratio, directly was related to lipoprotein particle size and the risk of atherosclerosis.[17,18]

Previously, modulatory effects of sesame on lipid metabolism and hypocholesterolemic properties of sesame seeds, sesame lignans, or sesame oil were investigated in animal studies. Administration of sesame seed powder to hypercholesterolemic rats resulted in a significant decrease in plasma and liver total lipid, cholesterol concentrations, plasma LDL-C, and an increase in plasma HDL-C levels; these lipid-lowering effects of sesame were related to increased fecal excretion of cholesterol, neutral sterol, bile acid, and up-regulated hepatic 3-hydroxy-3-methylglutaryl-CoA reductase activity.[19] In another study, TC, non-HDL-C, plasma lipid, and LDL-C peroxidation decreased and HDL-C increased following sesame supplementation in diabetic rats.[5] Addition of sesame seeds with high concentration of sesamin and sesamolin at levels of 200 g/kg to the experimental diet of rats, increased both hepatic mitochondrial and peroxisomal fatty acid oxidation, and also increased activity of fatty acid oxidation enzymes such as acyl-CoA oxidase, carnitin palmitoyltransferase, 3-hydroxyacyl-CoA dehydrogenase, and 3-ketoacyl-CoA thiolase; in contrast, sesame supplementation down-regulated enzymes involved in fatty acid synthesis including fatty acid synthase, glucose-6-phosphate dehydrogenase, ATP-citrate lyase, and pyrovate kinase.[20] In another experiment, a 15-day sesamin supplementation in rats could decrease the mRNA levels of sterol regulatory element binding protein-1 (SREBP-1), a key transcription factor which is involved in the biosynthesis of cholesterol and fatty acids.[21] Sesame lignans have the potential to decrease 3-hydroxy-3-methyl-glutaryl-CoA reductase activity, rate-limiting enzyme in cholesterol biosynthesis, inhibit acyl-CoA cholesterol acyltransferase activity, a main target of cholesterol-lowering drug treatment, and also induce a moderate increase in 7-α-hydroxylase activity, rate-limiting enzyme in bile acid biosynthesis from cholesterol.[22,23]

In human, there are limited studies that investigated the potential efficacy of sesame or its byproducts, on lipid profiles and other

Table 3. Comparison of the nutritional composition of the two breakfast meal patterns

Parameters	Baseline values	
	Ardeh *(n = 20)*	Control *(n = 16)*
Wheat bread, *g*	30	60
Cheese, *g*	- - -	30
Ardeh, *g*	28	- - -
Tea, *cup*	1	1
Sugar, *g*	5	5
Energy, *kcal*	271	269
Carbohydrate, *g*	29.06	42.5
Protein, *g*	7.54	9.8
Total fat, *g*	15.24	6.7
Saturated fat, *g*	2.24	4.47
Monounsaturated fat, *g*	6.04	1.38
Polyunsaturated fat, *g*	7.01	0.18
Dietary fiber, *g*	3.21	1.3

Nutritional composition of both breakfast meal was determined using the Nutritionist Software, version 4.

Table 4. Lipid profiles and atherogenic lipid parameters after a six- week intervention[1]

Parameters	Adjusted mean		*P for treatment effects* [2]
	Ardeh *(n = 20)*	Control *(n = 16)*	
Total cholesterol, *mg/dL*	189 ± 7.6	188 ± 8.8	0.98
Triglycerides, *mg/dL*	144 ± 9.8	175 ± 11.4	0.04
HDL-C, *mg/dL*	51.4 ± 1.6	46.8 ± 1.8	0.07
LDL-C, *mg/dL*	109 ± 6.3	104 ± 7.3	0.55
Total cholesterol/HDL-C ratio	3.92 ± 0.25	4.14 ± 0.30	0.61
LDL-C/ HDL-C ratio	2.26 ± 0.19	2.27 ± 0.23	0.92
Atherogenic index of plasma	0.42 ± 0.04	0.54 ± 0.05	0.05

[1] Data are adjusted mean ± SEM; [2]Analysis of covariance was used with adjustment for baseline values as covariate.

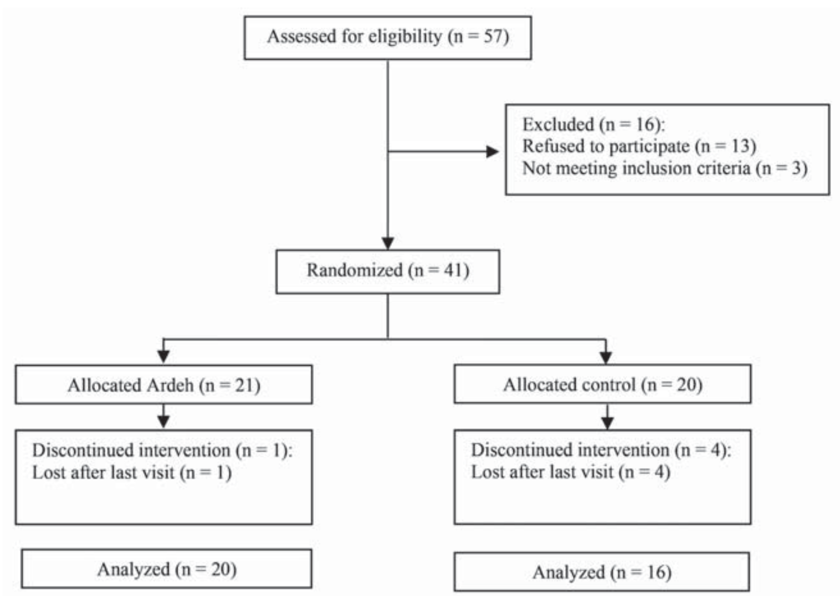

Figure 1. Flow chart of the study.

cardiovascular risk factors, and the results are inconsistent. In a randomized cross-over study, supplementation with 25 g/d sesame seeds (provided ~ 50 mg/d sesame lignans) for five weeks in overweight and obese had no beneficial effects on lipid profiles, blood pressure, and other cardiovascular risk factors including systemic inflammation and oxidative stress;[9] in contrast, replacement of a part of daily energy intake with 40 g/d roasted sesame in 21 hyperlipidemic patients, significantly decreased TC and LDL-C along with enhancement of LDL-C particles to oxidation.[12] Substitution of 35 g/d sesame oil as the only edible oil for 45 days in hypertensive women resulted in significant decrease in serum TG and thiobarbituric acid reactive substances, systolic and diastolic blood pressure, and BMI.[10] The lack of a control group is considered as a main weakness of these studies. In one open label study, type 2 diabetics who received 35 g/d sesame oil for 60 days, had significant reduction in serum TC, LDL-C, and TG levels.[11]

The present study had a few limitations; the duration of the study was limited and the HbA1c levels were not measured at baseline and after the treatment. In addition, it should be noted that a part of the changes observed in lipid profile in the Ardeh group may be due to elimination of cheese from the usual breakfast meal of the patients.

In the present study, the effects of Ardeh, as a traditional and unique functional food, on serum lipids, lipoproteins, and athero-

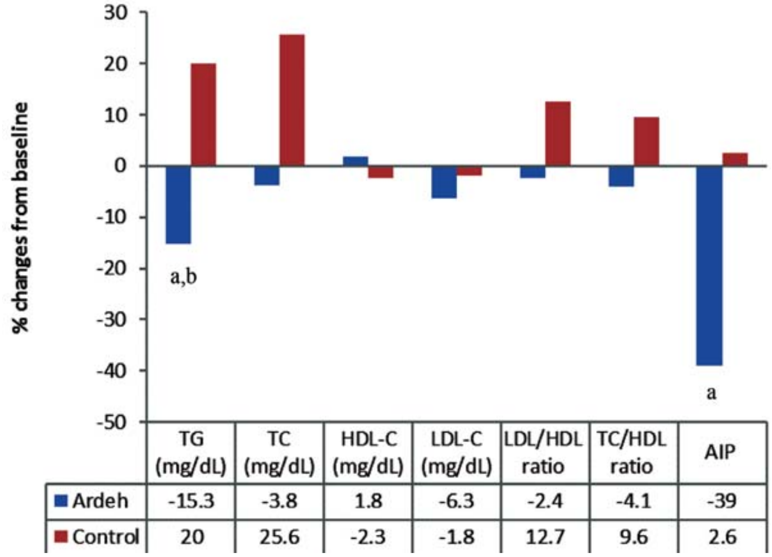

Figure 2. The mean % changes of the lipid profiles and atherogenic lipid parameters in the groups; [a]significant difference from baseline ($P < 0.05$; Student paired t-test was used); [b]significant difference from the control group ($P < 0.05$; t-test was used); TG: triglycerides; TC: total cholesterol; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; AIP: atherogenic index of plasma.

genic lipid parameters in type 2 diabetic patients were investigated. The results showed that replacing a part of regular diet with Ardeh could have favorable effects on modulation of dyslipidemia and atherogenisity of lipid profiles in type 2 diabetic patients.

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