Original Article

Pistachio Nut Effects on the Blood Lipid Profile in Patients With Type II Diabetes Mellitus: A Single-Blind Randomized Crossover Controlled Clinical Trial

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ABSTRACT

Introduction: Nuts are known for their health properties, and they play a special role in Mediterranean diets. This study aimed to determine Iranian pistachio effects on serum lipid levels in type II diabetic patients.

Methods: In this randomized crossover single-blind trial, 48 diabetic patients were randomly assigned to 2 groups: one that consumed 50 g of Iranian pistachios and one that followed the usual diet for 12 weeks. After an 8-week washout period, the participants were crossed over to the alternate arm.

Results: Systolic blood pressure was significantly lower in the pistachio phase than the usual diet. Changes in diastolic blood pressure, lipid values (cholesterol, triglyceride, low-density lipoprotein, and high-density lipoprotein), weight, and body mass index were not significantly different between the 2 intervention phases.

Conclusions: In diabetic patients, an Iranian pistachio intake (50 g daily) improved systolic blood pressure. Additionally, no detrimental effects were caused by pistachio consumption on lipid values. It seems that pistachio consumption at a high dose could change the results. ***(Iranian Heart Journal 2021; 22(3): 23-32)***

KEYWORDS: Type 2 diabetes, Pistachio nut, Serum lipid, Systolic blood pressure

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Type II diabetes, as an important health problem and a major risk factor for cardiovascular diseases, can affect life expectancy and the quality of life. [1] Several epidemiological and clinical studies have documented a rapid increase in the prevalence of diabetes and impaired glucose tolerance among the global population. [1-3] Esteghamati et al [4] found that in a 7-year period (2005–2011), trend analysis revealed more than a 35% increase in the prevalence of diabetes mellitus in Iran. Insulin resistance is a major cause of this chronic disease. Diabetes is characterized by hyperglycemia and dyslipidemia. [2] Dietary modifications and some lifestyle recommendations are important means of preventing type II diabetes and controlling its complications such as dyslipidemia. [5, 6]

Patients with diabetes could have various types of dyslipidemia. Diabetic dyslipidemia is characterized by elevated plasma triglyceride and low-density lipoprotein (LDL), as well as reduced levels of high-density lipoprotein (HDL). [7] Certain foods, especially staple foods such as whole grains, fruits, nuts, and vegetables, have been linked to decreased risks of developing diabetes. [8] Of the aforementioned foods, nuts have attracted the attention of researchers because of their nutrient content. [8] Jiang et al [5] (2002) suggested that higher consumption of nuts and peanut butter could have potential benefits in lowering the risk of type II diabetes.

Nuts are high in fat; nonetheless, despite their fat content, they are recognized as "heart-healthy" by the United States Food and Drug Administration. [9] Some studies have shown that types of dietary fat other than the total fat intake could predict the risk of diabetes. [5, 10] Fat constitutes 70% to 80% of nut composition, and most fatty acids in nuts are unsaturated (poly- and monounsaturated fatty acids). [5] Nuts are also a good source for some other nutrients such as magnesium, fiber, vitamins, minerals, antioxidants, and plant polyphenols, all of which have beneficial effects on health. [5] In several clinical and epidemiological studies, results have shown an inverse association between nut consumption and blood lipids. [5, 8] Most of the recent studies have focused on the lipid-lowering effects of nuts. [9, 10]

Pistachios, as a member of tree nuts, constitute a better source of plant protein, phytosterols, potassium, vitamin B6, and vitamin A. [8, 11, 12] In recent years, some studies have focused on the bioactive compounds of pistachios. [13] Mandalari et al [14] found that polyphenols, xanthophylls (lutein), and tocopherols from pistachios (raw or roasted) are released rapidly in the stomach and absorbed in the duodenum and that this bioaccessibility of bioactive compounds could explain the health-related effects of pistachio consumption.

To investigate the health effects of pistachios, Sari et al [15] enrolled 32 healthy young men in a clinical trial study. A Mediterranean diet was prescribed for 4 weeks; then, pistachios were added for the next 4 weeks through the replacement of 20% of the daily caloric intake of monounsaturated fat content. The authors found that compared with the Mediterranean diet, pistachios decreased glucose, LDL, cholesterol, and triglyceride. They concluded that pistachio consumption could improve blood lipids and some inflammation indices. Sheridan et al [16] (2007) mentioned that 4 weeks of pistachio consumption in 15 subjects with moderate hypercholesterolemia significantly reduced total cholesterol/HDL and LDL-C/HDL-C ratios and significantly increased HDL-C levels.

The objective of the present study was to explore the effects of pistachio consumption for 12 weeks on the lipid profile of diabetic patients.

METHODS

Subjects

Forty-eight type II diabetic patients were recruited in a single-blind randomized crossover clinical trial. The demographic characteristics of the study population are summarized in Table 1. The eligibility criteria consisted of patients with diabetes of at least 1 year's duration, not taking multivitamin supplements within 1 month before the study, treatment with oral hypoglycemic agents, having normal levels of serum creatinine, and liver function tests within the normal range.

Participants presenting with pregnancy or pregnancy planning, heart failure based on self-report or clinical examination, and the need for the prescription of insulin were excluded.

Sample Size

The sample size of the study was calculated by using the data of fasting blood glucose in a previous study [15] and according to the following formula:

$$N = \frac{\left(S_1^{\,2} + S_2^{\,2}\right)\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{\left(M_2 - M_1\right)^2}$$

where N =sample size, α = 0.05, β =0.2, Z =1.96, M1 =91, M2 =82, S1 =8, and S2 =6. The desired sample size for our study was 16 subjects in each group; nevertheless, our true sample size was 30 diabetic patients in each group.

Experimental design

After enrolment, baseline demographic data were recorded for all the participants and they were asked to consume a diet similar to the past 6 months and do not alter their diet and physical activity during the study. All the subjects participated in a baseline evaluation period that included food recording for 3 days and instructions for the recording of foods, the measurement of blood pressure, and anthropometric indices (weight and height and the calculation of body mass index). On the next day, fasting blood was obtained to measure fasting plasma glucose; liver function tests, including serum aspartate aminotransferase and alanine aminotransferase; serum creatinine, C-reactive protein, and insulin. Patients with normal creatinine and liver function tests were included in the study.

The study was conducted in Shahid Beheshti Hospital of Qom, Iran, from February 2012 through March 2013. The Ethics Committee of the Qom University of Medical Sciences, Qom, Iran, approved the study protocol (IRCT138809282890N1). All the subjects were aware of the content of the study; and if they agreed to participate, a written informed consent form was obtained.

Afterward, the participants were randomly assigned to Group A or Group B via block randomization. The Group A participants followed their routine diet and consumed 50 g of raw pistachios per day at morning and evening snack times for 12 weeks, while the Group B participants followed their routine diet for 12 weeks. Each subject followed the 2 diets and had an 8-week washout period. The adherence to pistachio consumption was determined after the initiation of the study every 4 weeks. For the maximization of the adherence of the subjects, pistachios were supplied by the research team and each daily dose was pre-packaged in 2 bags (totally, 50 g per day). The subjects were instructed to consume pistachios at snack time on the morning and evening of each day. After 12 weeks, at the end of Stage I, all the laboratory tests and clinical evaluations were repeated in the same manner as the initial visit.

Four patients did not complete the study (1 patient in Group A and 3 patients in Group B). Two patients started insulin therapy (1 patient in each group), and they were excluded from the study. Two patients were withdrawn because of poor compliance with the protocol of the study. Finally, 44 patients completed both phases of the study (23 patients in Group A and 21 patients in Group B). The study protocol is shown in Figure 1.

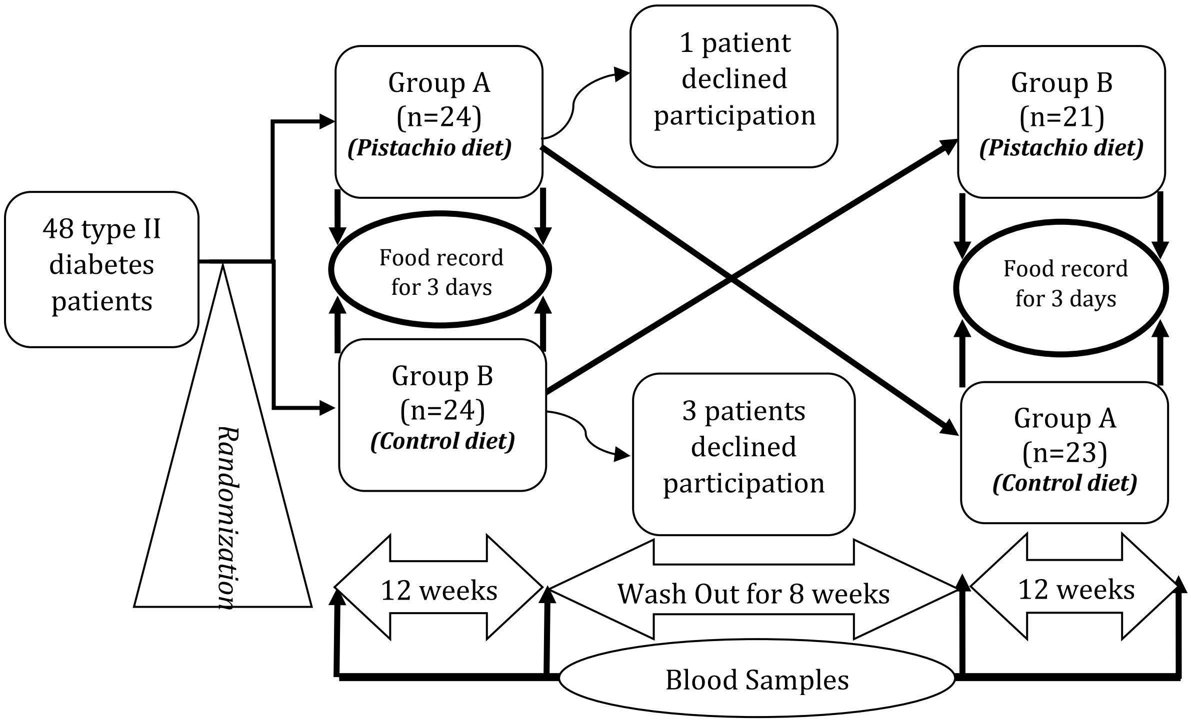

Figure 1. The image depicts the study design.

Measurements

Body weight was measured while the subjects were minimally clothed, without shoes, using digital scales and recorded to the nearest 0.1 kg. Height was measured in a standing position, without shoes, using a tape meter while the shoulders were in a normal state.

The lipid profile for each patient was measured before and after each phase. Blood samples were collected after overnight fasting. A measure of 10 mL of blood was collected at each draw. Then, serum triglyceride, total cholesterol, and HDL and LDL cholesterol were measured. Total cholesterol, triglyceride, and HDL cholesterol were measured by enzymatic procedures (Pars Azmun, Iran). LDL cholesterol was determined indirectly according to the Friedewald formula. [17]

Diet Analysis

Adherence to the normal diets and possible changes were carefully monitored by using food record questionnaires, which were completed in 12 days in 4 separated phases (Fig. 1). The nutrient composition of the diets was calculated using the Nutritionist 4 software.

Statistical Analysis

Ordinary least square estimators were derived using the SAS proc Generalized Linear models (GLM). The study had a run-in as well as a washout period.

The data were evaluated for potential carryover effects. For the assessment of potential carryover effects or treatment-period interactions due to the crossover design, potential covariates such as fasting blood sugar, lipid values, systolic and diastolic blood pressures, and weight, as well as test order, were assessed. If the carryover test was significant (P <0.1), then the 2 treatments were compared using only the Stage I data as in a parallel-group design.

If treatment by period interaction was significant, then the 2 treatments were compared using a separate analysis within each period. In this situation, GLM repeated measure analysis was conducted.

RESULTS

Patient Characteristics

Forty-four diabetic patients completed the study protocol. The baseline characteristics of the participants of the 2 groups are depicted in Table 1. There were no significant differences (*P* >0.05) between the 2 groups in terms of age, body weight, blood glucose, and lipid profile before the beginning of each experimental phase.

Dietary Intake

The results of the repeated measure ANOVA for the dietary intake of the participants in the 4 periods, based on the results of the 3-day diet records, are presented in Table 2. These results show some significant changes in dietary intake between the stages. Although the study participants were asked to adhere to their routine diets (Table 2), the level of vitamin C before Stage I was higher in Group A, the cholesterol intake before Stage II was higher in Group B, and the carbohydrate intake was higher after Stage II in Group A. Except for these nutrients, there were no significant differences in terms of the other food indices (*P* >0.05).

Effects on Serum Lipids and Lipoproteins

The findings vis-à-vis the mean difference in lipid values and weight are reported in Table 3.

The results for the carryover, treatment-period interactions, and treatment effects on lipid values, fasting blood sugar, and weight are reported in Table 4. As is shown in Table 4, there were significant carryover effects for triglyceride and HDL, in conjunction with significant treatment-period interaction effects for systolic blood pressure and HDL.

Overall, with respect to systolic blood pressure, there were no significant effects on blood values.

Table 1. Baseline characteristics of the study patients

Variable	Group A	Group B	*P*-value
Age (y)	53.1±10.1	50.1±10.8	0.478
Diabetes duration (y)	6.7±5.7	7.7±4.7	0.221
Weight (kg)	72.6±8.4	78.9±12.7	0.57
Body mass index (kg/m²)	30.3±4.1	31.8±7.3	0.099
Fasting blood sugar (mg/ dL)	153±1	145.9±34.6	0.539
Hemoglobin A1C (mg/dL)	8.2±1.7	7.5±1.1	0.092
Total cholesterol (mg/dL)	162.3±38.3	172.1±27.3	0.337
Triglyceride (mg/dL)	165.5±107.4	147.9±60.5	0.502
Low-density lipoprotein (mg/dL)	75.3±23.8	79.1±28.4	0.631
High-density lipoprotein (mg/dL)	53.8±9.8	58.9±9.9	0.097
Systolic blood pressure (mm Hg)	133.1±16.4	128.6±21.7	0.443
Diastolic blood pressure (mm Hg)	82.6±9.6	78.1±10.8	0.122

Table 2. Dietary intake of the subjects separately by intervention periods

Stages and Groups / Variables	Stage I				Stage II				*P*-value **
	Group A		Group B		Group A		Group B		
	Before	After	Before	After	Before	After	Before	After	
Energy	2253.3±824	2367±320.2	2037.9±423	1985.5±343.5	1889.8±593.6	2195.6±795	2207.1±475.2	2264.9±480.4	0.573
Protein	79.5±34	88.4±10.7	66.4±17.9	69.6±16.5	75.2±36.7	73.4±21.6	90.3±36.7	89.4±18.8	0.097
Carbohydrate	304±82	303±71.2	266±68.2	241.3±78	226.9±51	304±107	224.6±52.3	229.9±50.5	0.012*
Fat	83.5±50.5	96.5±18.1	82.9±40.4	85.6±32.9	75.2±36.7	80.6±42.1	108.7±41.8	115.3±37.3	0.42
Dietary fiber	19.2±5.7	21.6±5.3	14.3±6.4	13.2±4.6	15.3±7.1	16±8.4	18.4±12.1	19.8±8.4	0.571
Monosaccharides	62±37.2	48.6±26.2	57±32.6	50.4±28	60.7±26.6	66.6±33.1	51.7±22.7	34.5±16.1	0.38
Cholesterol	197.7±120.6	185.1±71.9	213.5±207.1	258.8±184	242.4±204	208.4±134.8	280.2±145.6	182.2±108	0.025*
Vitamin A	513±349.9	568.4±518.7	558.1±388	1010±1731	346.6±238.5	1274.8±1576	538.7±525.5	571.1±464.3	0.35
Vitamin E	2.7±2.3	1.92±1.7	2.5±2.8	3.4±3.4	3.7±4.4	2.4±3	2.6±2.9	1±1.3	0.48
Vitamin C	217.7±75.9	103.5±55.6	153.9±81.6	99.6±74	76.1±68.4	121±99	99.7±66.9	94.8±65.9	0.01*
Beta-carotene	272.2±282	267.4±442.8	204.7±292.9	249.6±401	99.9±111.8	721±1638	315.1±490.4	347.1±422.8	0.575
Selenium	0.06±0.07	13.8±45.6	0.05±0.04	0.07±0.07	0.07±0.06	0.05±0.04	0.05±0.04	0.06±0.05	0.185

* Data are shown as mean± SEM.
** Repeated Measure

Table 3. Mean difference of biochemical parameters in the 2 groups

Variables	Group A			Group B			Total Difference
	Before	After	Mean Differences	Before	After	Mean Differences	
FBS	147.09±37	144.2±32.3	-2.81	147.6±40.5	151±42.3	3.76	-6.57
Cholesterol	165.6±27.1	159.6±29.4	-6.04	167.5±33.6	163.7±26.7	-3.73	-2.31
Triglyceride	142.9±66.5	135±64.6	-7.9	122.9±57.2	126.8±58.3	-1.15	-6.75
SBP	125.2±15.6	119.2±12.1	-6.02	121±12.4	118.3±12.4	-2.62	-3.4
DBP	79.7±8.4	77.9±10	-1.81	77.9±9.07	77.44±10.4	-0.46	-1.35
HDL	53±11	51.5±9.8	-1.6	56.2±10	52.5±9.7	-6.48	4.88
LDL	79.6±23.6	82.41±27.2	2.74	78.6±23.5	82.6±22.2	3.98	-1.24
Weight	75.6±10.3	73.8±9.9	-1.8	75.58±11	72.7±10.5	-2.79	0.99
BMI	31.2±5.5	30.6±5.4	-0.6	31.5±5.93	30.4±5.6	-1.1	0.5

FBS, Fasting blood sugar; SBP, Systolic blood pressure; DBP, Diastolic blood pressure; HDL, High-density lipoprotein; LDL, Low-density lipoprotein; BMI, Body mass index

Table 4. Carryover effects, treatment–period interactions, and treatment effects

	P-value		
Variables	Carryover Effects	Treatment -Period Interactions	Treatment Effects
FBS	0.95	0.33	0.36
Cholesterol	0.74	0.49	0.49
Triglyceride	0.04	0.9	0.17
SBP	0.18	0.06	0.038*
DBP	0.25	0.53	0.98
HDL	0.0004	0.0026	0.57
LDL	0.69	0.52	0.71
Weight	0.17	0.35	0.27
BMI	0.12	0.16	0.18

FBS, Fasting blood sugar; SBP, Systolic blood pressure; DBP, Diastolic blood pressure; HDL, High-density lipoprotein; LDL, Low-density lipoprotein; BMI, Body mass index

DISCUSSION

In the present randomized crossover trial, 44 diabetic patients consumed 50 g of Iranian pistachio nuts for 12 weeks. We observed that the consumption of pistachios reduced resting systolic blood pressure, but it did not improve the body weight and lipid profile of the participants.

To our knowledge, this is the first study on the effects of pistachios on lipid profile and weight. Iranian pistachios, similar to other pistachio variants, constitute a good source of mineral and active plant compounds such as phytosterols. Moreover, Iranian pistachios are deemed a rich source of iron. Indeed, the iron content of these pistachios is 10 times that of the US type. [18] According to a recently published study, the presence of a food matrix (muffin) could decrease bioavailability in some pistachio bioactive compounds. [14]

Fasting Blood Sugar

Kendall [19] and Hernández-Alonso [20] found that pistachio consumption could improve glucose response. Nonetheless, in our study, 4 weeks of pistachio consumption did not affect fasting blood sugar. In contrast, according to a previous investigation analyzing data by using the paired *t* test, pistachio consumption improved fasting blood sugar. [21] In a randomized control trial, after 6 weeks of a pistachio diet (20% of daily energy), significant improvements were reported in fasting plasma glucose. [22] Still, according to Anderson et al, [23] 6 weeks of pistachio consumption failed to improve fasting blood glucose or insulin concentrations.

Lipid profile

West et al, [24, 25] in randomized crossover trials, enrolled 30 diabetic patients. The participants consumed a controlled diet (27% total fat and 7% saturated fat) or a pistachio diet (33% total fat and 7% saturated fat) for 4 weeks. In the pistachio diet, the participants consumed pistachios equivalent to 20% of their daily calories (2–5 ounces per day). The pistachio diet, in comparison with the control diet, reduced ambulatory systolic blood pressure, fasting triglyceride, and the total cholesterol to HDL cholesterol ratio, [24] but it failed to affect resting systolic blood pressure. [25] A recent investigation reported a significant improvement in total cholesterol and LDL but no changes as regards HDL and triglyceride. [22] Burns-Whitmore [26] reported that although pistachio consumption after 10 weeks reduced lipid profile (ie, LDL, total cholesterol, and triglyceride) in their study population, this reduction was not significant. Moreover, improvements in systolic and diastolic blood pressures did not alter significantly. Elsewhere, Sheridan et al [16] reported a significant increase in HDL and no statistically significant changes in triglyceride, cholesterol, or blood pressure after 4 weeks of dietary modifications with 15% caloric intake from pistachios.

Body weight

According to Gulati et al, [22] although body weight did not change after 6 weeks of pistachio consumption, waist circumference significantly improved (P =0.02) in their patients suffering from metabolic syndromes. However, another study showed that 10 weeks of pistachio consumption (20% of energy) did not significantly change body weight or waist circumference in healthy females. [26] Anderson et al [23] found that 35.4 g of pistachios at bedtime in overweight subjects did not decrease body weight after 6 weeks. Additionally, they reported that 4 weeks of 15% of caloric intake from pistachio nuts did not change body weight in their subjects.

In this study, we added pistachios to the routine diet of the participants, while the aforementioned studies assigned pistachio

diets as 20% of daily energy requirements [22, 26] or replaced carbohydrates or fat intakes with pistachios. [19, 24, 25] The lipid profile of pistachios contains unsaturated fatty acids and bioactive polyphenols. We, therefore, expect that the consumption of pistachios could improve lipid profile, blood glucose, and even body weight. [23]
It seems that the pistachio prescription in our study was limited and that it might not have been enough to affect our indices.
We have some limitations in our study. First, it seems that the washout period (8 wk) was not long enough (according to significant carryover effects in 3 variables). Still, our washout period is longer than that in similar investigations by Hernández-Alonso, [20] West, [24] and Sauder. [25] Future research on this topic should consider longer washout periods for the elimination of carryover effects.
Another weakness of note is that we did not measure ambulatory blood pressure. Pistachio consumption could decrease resting systolic blood pressure; nonetheless, according to a recent study, [25] we recommend that the measurement of ambulatory blood pressure is more beneficial.
Moreover, pistachios are a rich source of polyphenols and phytosterols, which possess antioxidative properties. [25, 27] According to a recent investigation, pistachio consumption for 18 days could alter gut microbiota, especially butyrate-producing bacteria. [28]
Unfortunately, we did not measure oxidative or inflammation indices (except for C-reactive protein, which did not alter after pistachio consumption). Hence, we recommend that these indices be controlled in future studies on Iranian pistachios.

CONCLUSION

The results of the present study showed no significant effects after interventions with pistachios for 12 weeks on serum lipid in diabetic patients. However, given the short washout period in this study, further research is warranted.

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