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Statins and almonds to lower lipoproteins (the STALL Study)

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BACKGROUND: Dietary supplementation with almonds has demonstrated dose-dependent decreases in low-density lipoprotein cholesterol (LDL-C), likely because of their composition of beneficial nutrients including mono- and polyunsaturated fatty acids, fiber, and protein.

OBJECTIVE: The primary objective of this study was to determine the changes in the lipid profile (LDL-C, high-density lipoprotein cholesterol [HDL-C], triglycerides, total cholesterol, non–HDL-C), LDL-C particle size, and lipoprotein (a) when 100 g of almonds daily were added to background statin therapy for 4 weeks.

METHODS: Subjects (N = 48) receiving a consistent statin dose were randomized to 100 g of almonds daily and to The National Cholesterol Education Program Adult Treatment Panel's third report Therapeutic Lifestyle Changes Diet counseling (almond group; n = 22) or solely Adult Treatment Panel's third report Therapeutic Lifestyle Changes Diet counseling (non-almond group; n = 26), for 4 weeks.

RESULTS: No significant changes in weight and weekly physical activity were noted between the 2 groups from baseline. However, the almond group consumed significantly more calories at 4 weeks compared with controls. The almond group experienced a 4.9% reduction in non–HDL-C compared with a 3.5% increase for the non-almond group ($P = .02$). Additionally, notable improvements were observed in LDL-C and triglycerides, but did not achieve statistical significance ($P = .068$ for both parameters). There was also a shift from LDL pattern A to pattern B particles ($P = .003$) in the almond group. No significant differences in total cholesterol ($P = .1$), HDL-C ($P = .3$), or lipoprotein (a) ($P = .1$) were observed.

CONCLUSION: Adding 100 g of almonds daily to chronic statin therapy for 4 weeks significantly reduced non–HDL-C.

Trial registration: clinicaltrials.gov Identifier: NCT00603876.

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Introduction

Coronary heart disease (CHD) continues to be the leading cause of morbidity and mortality in the United States, affecting an estimated 16.3 million individuals ≥20 years old or approximately 7% of the total population.[1] Elevated low-density lipoprotein cholesterol (LDL-C) is a major modifiable risk factor for CHD. The National Cholesterol Education Program Adult Treatment Panel's third report (ATP-III), the National Lipid Association (NLA) Recommendations for Patient-centered Management of Dyslipidemia: Part 1 – Executive Summary, and the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the ACC/AHA Task Force on Practice Guidelines, all focus on evidence demonstrating the importance of LDL-C reduction to decrease CHD risk.[2–4] Furthermore, ATP-III identifies non–high-density lipoprotein cholesterol (non-HDL-C) as a secondary target in patients with triglycerides (TG) ≥200 mg/dL, whereas the NLA classifies non–HDL-C as a primary target to reduce CHD risk.[2,3] Additionally, the ATP-III guidelines consider lipoprotein(a) [Lp(a)] as an emerging risk factor that has been linked to CHD risk.[2] In addition to focusing on lipid biomarkers, ATP-III also emphasizes a healthy diet and regular exercise for patients regardless of LDL-C to decrease their risk for CHD.[2] This healthy lifestyle is also supported by the more recent NLA Recommendations and the ACC/AHA Guideline on Lifestyle Management to Reduce Cardiovascular Risk.[3,5]

Therapeutic Lifestyle Changes (TLC) described in ATP-III advocate a comprehensive lifestyle approach to CHD risk reduction.[2] In addition to weight reduction and physical activity, ATP-III promotes the TLC Diet. This approach emphasizes a reduction in saturated fatty acids (<7% of total daily calories) and moderate consumption of unsaturated fats, specifically monounsaturated fatty acids (MUFA) and polyunsaturated fatty acids (PUFA). Diets considered "heart healthy" (ie, Mediterranean Diet) frequently replace saturated fats with foods high in unsaturated fat such as nuts and olive oil. One hundred grams of almonds contain approximately 32 g of MUFA, 12 g of PUFA, and 4 g of saturated fatty acids.[6] Additionally, almonds contain fiber, plant protein, phytochemicals, and sterols, all of which may contribute to their beneficial effects on lipoproteins.[7,8]

Although almonds are high in unsaturated fats, protein, and fiber, they are also energy-dense (Table 1).[6] One hundred grams of almonds contain approximately 579 kcal.[6] Thus, patients may risk gaining weight when adding them to their habitual diet. However, studies in general have not found significant increases in weight with varying amounts of almond intake.[9–16] It has been proposed that the protein and fiber content of almonds promotes satiety, therefore decreasing caloric intake from other foods and reducing the propensity for weight gain.[16,17]

Table 1 Nutrient profile of almonds

Nutrient	Amount/100 g
Energy (kcal)	579
Protein (g)	21.2
Total fat (g)	49.9
Saturated fatty acids (g)	3.8
Monounsaturated fatty acids (g)	31.5
Polyunsaturated fatty acids (g)	12.3
Carbohydrate (g)	21.6
Fiber (g)	12.5
Sugars (g)	4.4

For most patients, statins are the cornerstone for LDL-C reduction. However, because of aggressive LDL-C treatment goals, cost, and dose-dependent side effects associated with statins, additional therapy may be required to achieve optimal LDL-C levels. One option that may further reduce LDL-C levels when added to statin therapy is incorporating almonds in a heart-healthy diet. Almonds induce a dose-dependent LDL-C lowering when consumption is >50 g daily.[8] To our knowledge, no study has assessed the lipid-lowering effects of almonds when added to statin therapy. Although 1 study by Jenkins et al, included 2 patients on statin therapy in their assessment of almonds in hyperlipidemic patients, the small sample size precludes definitive conclusions.[9] We hypothesized that consumption of 100 g of almonds daily would significantly and favorably affect LDL-C, HDL-C, TG, total cholesterol (TC), non–HDL-C, LDL-C particle size, and Lp(a) when added to chronic statin therapy.

Methods

Subjects aged 18 to 78 years taking chronic statin therapy, defined as a consistent statin dose for at least 8 weeks before study entry with continuation of the same dose during the 4-week study period, were eligible. Exclusion criteria included: LDL-C levels <70 mg/dL, the use of lipid-lowering agents other than statins, adherence to specialized diets, nut consumption greater than twice weekly, nut allergies, liver disease, chronic renal or CHD, and alcohol or illicit drug dependence. Postmenopausal women were allowed study entry if not taking hormone replacement therapy or on a consistent hormone replacement therapy dose. Females of child-bearing potential using an effective form of contraception were allowed to participate. Subjects meeting eligibility criteria were randomized to 100 g of almonds daily and ATP-III TLC Diet counseling (almond group) or solely ATP-III TLC Diet counseling (non-almond group). The University of Kansas Medical Center Human Subjects Committee, which serves as the institutional review board, approved the study, and all subjects signed informed consent before study enrollment. This study was registered at Clinicaltrials.gov as NCT00603876.