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Heart Bar Report

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Introduction

Recently Jenkins and colleagues(1) documented that a "portfolio diet" modestly restricted in saturated fat and cholesterol but including soluble fiber, soy protein, and plant sterols lowered LDL-cholesterol values by 30%, similar to the starting dose of a statin drug. In an editorial, I suggested that an AHA diet containing 4-6 grams of soluble fiber, 10 grams of soy protein twice daily, and 2 grams of plant sterols would achieve a similar result.(2) This study examined the effects of one bar twice daily on serum cholesterol values of hypercholesterolemic individuals.

Primary Objective

The primary objective was to determine if bars containing soluble fiber, soy protein and plant sterols would significantly lower serum cholesterol and LDL-cholesterol values over a 6-week period compared to a placebo bar.

Study Design

This was a pilot study to examine the effects of clinically proven ingredients when combined into a bar. After a screening visit (week -3 subjects returned for diet instruction on an AHA step I diet (week -2). At baseline (week 0 or day -1) subjects were instructed to use two enriched bars daily. They returned at 2, 4 and 6 weeks. The diet was reinforced at week 2 and 4 and blood lipid measurements were repeated at weeks 4 and 6. Twenty subjects were enrolled.

Bars

The chocolate-flavored enriched bars would provide 4 grams of beta glucan fiber, 10 grams of isolated soy protein, and 1.5 grams of plant sterols per bar.

Results

Twenty subjects (100%) completed 4 weeks and 18 subjects (90%) completed 6 weeks. The bars were well tolerated and did not interfere with study completion. A few subjects had mild abdominal fullness, increased gas and mild dyspepsia. Adherence to bar intake was excellent.

Outcome values are summarized in the table. Significant changes were seen in total serum cholesterol and LDL-cholesterol. No significant changes were seen in serum HDL-cholesterol, triglycerides, glucose, blood pressure or body weight.

Serum total cholesterol decreased significantly with the AHA diet and decreased further to 10.7% below initial values at 4 weeks with bar use. Serum LDL-cholesterol decreased significantly with the AHA diet and decreased further to 14.5% below initial values at 4 weeks. Eleven of 20 subjects (55%) had LDL-cholesterol reductions of >15% with 4 subjects (20%) having reductions of more than 30%.

Discussion

This pilot study indicates that intake of two bars containing soluble fiber, soy protein and plant sterols is associated with a substantial reduction is serum total and LDL-cholesterol. When used with an AHA step 1 modestly restricted in saturated fat and cholesterol a highly significant reduction is cholesterol and LDL-cholesterol was seen. Four subjects had LDL-cholesterol reductions of more than 30%-- equivalent to the starting dose of a statin drug—while 55% of subjects had reductions of >15%. Since doubling the dose of a statin only reduces serum LDL-cholesterol by 6%, these bars have very important hypocholesterolemic potential.

Table. Values at screening, baseline after ≥2 weeks on AHA diet, and at 4 and 6weeks using two bars daily.

Measurement Fasting values	**Screening**	**Baseline** %chg from Screening	**4 weeks** %chg from Screening	**6 weeks** %chg from Screening
No. of subjects	20	20	20	18
Cholesterol	232	-6.1	-10.7	-6.4
mg/dl (SEM)	3.6	1.4	2.6	1.8
P value		0.0005	0.0004	0.0003
LDL-chol.	149	-9.2	-14.5	-9.7
mg/dl (SEM)	3.1	2	3.5	2.4
P value		0.0004	0.0009	0.0007
HDL-chol.	54	2.7	-3.6	0.6
mg/dl (SEM)	3.3	1.7	2.8	2.6
Triglycerides	148	9.4	6.5	11.1
mg/dl (SEM)	16.7	9.1	8.8	9.3
Glucose	90	na	na	2.1
mg/dl (SEM)	1.9			2.2
Systolic BP	126	-2.1	0.8	-2.0
mmHg (SEM)	3.6	1.6	2.4	2.2
Diastolic BP	84	-3.8	-1.0	-4.4
mmHg (SEM)	1.9	1.9	2.4	2.4
Weight	173	-0.2	-0.1	-0.1
lbs (SEM)	5.5	0.2	0.3	0.5

na= not available

Reference List

1. Jenkins DJA, Kendall CWC, Marchie A et al. A dietary portfolio of cholesterol lowering foods versus a statin on serum lipids and c-reactive protein. J Amer Med Assoc 2003;290:502-10.

2. Anderson JW. Diet first, then medication for hypercholesterolemia. J Amer Med Assoc 2003;290:531-3.