TITLE

Effect of daily use natural astaxanthin on C-reactive protein.

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ABSTRACT

Previous studies have provided data suggesting that daily use of natural astaxanthin can positively address inflammatory conditions such as rheumatoid arthritis and carpal tunnel syndrome. In this study, the effect of daily use of BioAstin™, a microalgae extract containing natural astaxanthin, on C-reactive protein was evaluated. It was found that after daily use of BioAstin for eight weeks C-reactive protein (CRP) was significantly lowered in the treatment group as compared to the placebo group. This correlation of reduced CRP and use of BioAstin™ may suggest that daily use can help reduce CRP and possibly lower inflammation levels in the body.

INTRODUCTION

Previous work has indicated that consumption of natural astaxanthin may have a positive effect on inflammatory conditions such as rheumatoid arthritis and carpal tunnel syndrome. This study investigated the effect of BioAstin™, a microalgae extract containing natural astaxanthin, on the serum level of C-reactive protein (CRP). The study was a single-center, placebo-controlled, parallel study of eight weeks in duration. C-reactive protein (CRP) is one of the acute phase proteins that increase during systemic inflammation. It has been suggested that testing CRP levels in the blood may be a new way to assess cardiovascular disease risk, according to the American Heart Association. Other research suggests that systemic or silent inflammation may be implicated in many life threatening diseases, such as cancer, heart disease, stroke, diabetes and Alzheimer's, among others.

MATERIALS AND METHODS

Subjects

Subjects were recruited from the San Francisco Bay Area through newspaper advertisements. Volunteers were admitted into the study if they qualified according to the following inclusion criteria: (1) men and women 40 to 60 years older, excluding pregnant and lactating women; (2) no diagnosis of cardiovascular disease, kidney disease, diabetes, or cancer; (3) on stable doses of medication, if taking any; (4) not participating in any other study that might conflict in some way with this one. Thirty-three participants were selected according to the above criteria and agreed to participate in the study. Eight subjects were lost to follow-up due to time conflicts with the end-of-study blood draw, and twenty-five subjects (16 men and 9 women) completed the study (Appendix 1). The study protocol had been approved by an independent investigational review committee and was explained to each subject who then signed an informed consent.

All subjects were instructed to continue their current prescription medications, over-the-counter preparations and supplements; not to change their diet or lifestyle; and to notify investigators of any change they or their health care professionals may make in their medication(s) during the study period. They were also instructed to

maintain their usual intake of coffee, tea, alcoholic beverages and soft drinks; their exercise routine; and not to make any special effort toward changing their weight.

Treatment

Subjects in the treatment group consumed three BioAstin softgel capsules per day, one with each meal for a period of eight weeks. Each BioAstin softgel capsule contained 4 mg of natural astaxanthin, 40 mcg of lutein, 65 IU of vitamin A (as beta-carotene), 10 IU of vitamin E, gelatin and safflower oil. Subjects in the placebo group consumed three placebo softgel capsules per day, one with each meal for a period of eight weeks. The placebo softgel capsules contained only safflower oil. Both the BioAstin and placebo softgel capsules had a total weight of 750 mg (500 mg of contents and 250 mg of gelatin) and were opaque such that it was not obvious to the investigator or to the subject which softgel capsule contained the treatment or the placebo.

Study Design

This single-center, double-blind, placebo-controlled study was conducted over an 8 week duration. Thirty-three subjects began the initial stages of the study, with a total of twenty-five subjects completing all aspects of the study (17 in treatment group, 8 in placebo group). Subjects were asked to give two fasting blood draws: one prior to starting the study; and one at the end of the study (eight weeks).

Beginning and post-study blood samples were analyzed by Quest Laboratories, San Jose, CA for CRP.

RESULTS

Table 1 presents blood chemistry data for CRP for twenty-five subjects, 17 in the treatment group and 8 in the placebo group. Data for each subject is presented in Appendix 1.

Table 1. C-Reactive Protein Measurements

	C-Reactive Protein (CRP) mg/dl	
Group	**Beginning**	**End**
Treatment	**1.35±1.55**	**1.07±1.35**
Placebo	**0.93±0.57**	**1.08±0.48**

DISCUSSION

The results of this study showed a significant decrease in the average CRP levels of the subjects who were in the treatment group. The mean of the pre-treatment CRP scores in the treatment group was 1.35, and the mean of the post-treatment scores was 1.07. These subjects, on the average, showed a 20.7% decrease in their CRP scores after taking the BioAstin for eight weeks. There was no such reduction in CRP scores in the placebo group, and in fact, the scores showed an average increase: the mean beginning score was 0.93 and the mean end score was 1.09.

Visual inspection of the CRP data presented in Appendix 1 showed substantial variance in the difference scores for subjects from pretest to post-test, even in the placebo group. The scores were not normally distributed, whether computed as simple difference of scores or as the percentage change in CRP levels, due to the presence of outliers. The non-normality of the scores made them inappropriate for parametric analysis. Therefore, a Mann-Whitney U-test was conducted to determine if there was a statistically significant difference between the change in CRP levels in the treatment and placebo groups. This is a nonparametric statistical test based on the relative rankings of the scores, from the lowest score (the largest decrease at post-test) to the highest score (the largest increase at post-test). The assumption is that if the treatment did reduce the CRP scores, the subjects in the treatment group would have lower rankings overall, and the subjects in the placebo group would have higher rankings. This analysis eliminates the potential biasing effect of outliers.

Despite the small sample sizes, the Mann-Whitney U-test revealed that there was a statistically significant difference between the groups in the raw difference scores between the beginning and end CRP values ($U = 37.5$, $n1 = 15$, $n2 = 8$: $p < .05$). Thus, there was a significantly greater reduction in the CRP levels in the subjects who received the BioAstin than in the subjects who received the placebo.

In conclusion, the study found that subjects who took BioAstin for eight weeks showed an average decrease in their measured CRP levels of over 20%. Subjects who took a placebo showed no decrease. Analysis of the data showed that there was a statistically significant difference between the two treatment conditions, suggesting that BioAstin may reduce CRP levels. This finding was based on small sample sizes, and should be replicated in a larger study. However, considering recent literature on the importance of CRP as an indicator of cardiac health and other life threatening issues, the finding of an average reduction in CRP after a regimen of BioAstin is a promising result that deserves further attention.

Appendix 1. Individual Patient C-Reactive Protein Data

Treatment

Sex	CRP Beg	CRP End	CRP Diff
F	6.30	5.30	-1.00
M	0.86	0.40	-0.46
M	1.08	0.61	-0.47
M	3.08	0.31	-2.77
F	0.24	0.15	-0.09
M	1.28	1.08	-0.20
M	1.37	2.23	0.86
F	0.41	0.35	-0.06
M	1.99	1.99	0.00
M	0.16	0.30	0.14
M	0.49	0.34	-0.15
M	0.16	0.24	0.08
F	0.43	0.31	-0.12
M	0.38	0.47	0.09
F	0.53	0.73	0.20
M	1.41	0.50	-0.91
M	2.76	2.83	0.07
Average	1.35	1.07	-0.28
Std Deviation	1.55	1.35	
Placebo			
M	1.21	1.70	0.49
F	2.00	1.51	-0.49
M	0.67	0.84	0.17
M	0.95	1.40	0.45
F	1.11	1.11	0.00
M	0.19	0.82	0.63
F	0.28	0.19	-0.09
F	1.01	1.10	0.09
Average	0.93	1.08	0.16
Std Deviation	0.57	0.48	