Open field, physician controlled clinical evaluation of a botanical weight loss formula based on *Garcinia cambogia* derived (-)hydroxycitric acid

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ABSTRACT

OBJECTIVE: *The purpose of this study was to evaluate the efficacy of (-)-Hydroxycitric acid (HCA) for body weight loss in overweight human subjects who received a (-)HCA formula consisting of 1500 mg of the calcium salt of HCA (750 mg of pure HCA) and 300 mcg of elemental chromium per day. (-)HCA derived from the rind of the Garcinia cambogia fruit competitively inhibits the cytosolic enzyme adenosine triphosphate (ATP) citrate lyase in vitro and in vivo. This mechanism occurs in experimental animals fed (-)HCA, and is likely responsible for their noticeably decreased feeding frequency, reduction in total body weight and body fat, and increase in energy expenditure.*

RESEARCH METHODS AND PROCEDURES: *This open field, physician controlled eight week clinical study was evaluated (-)HCA formula in 55 overweight subjects of both genders with a body mass index of >25 kg/m² and <45 kg/m².*

RESULTS: *Patients lost on average <5 lbs. after four and <10 lbs. after eight weeks of regimen on the (-)HCA formula ($p<0.001$). Weight loss was independent of the gender or age of the population studied. The blood levels of triglycerides (TG), VLDL in the entire population and LDL in men over 60 years of age were significantly ($p<0.05$) lowered during course of treatment (TG mean value before treatment 167 mg/dl vs. 155 mg/dl after eight weeks; VLDL 34 mg/dl before vs. 29 mg/dl after; LDL 124 mg/dl before vs. 116 mg/dl after), with the cholesterol levels unchanged. Blood levels of HDL were significantly ($p<0.01$) increased for the entire population studied (mean value before treatment 47 4 mg/dl vs. 50.4 mg/dl after). The eight week intake of the formula lowered the Coronary Heart Disease (CHD calculated as total cholesterol/HDL ratio)) risk index significantly ($p<0.01$) for the entire sample studied. The risk index decreased from a mean value of 0.99 (CI: 0.87-1.13) to a mean of 0.90 (CI: 0.76-1.04). No side effects of the regimen, subjective or objective, were reported.*

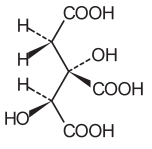
DISCUSSION

In view of safety of the regimen and significant weight loss effects and health benefits of the (-)HCA formula, it should be considered a promising supplement to weight loss therapy, especially when administered for several weeks.

INTRODUCTION

Hydroxycitric acid is an alpha-hydroxy tribasic acid (1,2-dihydroxypropane-1,2,3-tricarboxylic acid) with two asymmetric centers, hence the formation of two pairs of enantiomers or four different isomers, i.e. (-)hydroxycitric acid (I), (+)hydroxycitric acid (II), (-)allo-hydroxycitric acid (III), and (+)allo-hydroxycitric acid (IV) are possible (1-2). The (-)hydroxycitric acid (HCA) isomer is found in the rind of *Garcinia cambogia* fruit (fam. Clusiaceae) (Figure 1) (1-2). This isomer has been shown to be a potent linear competitive inhibitor of ATP citrate lyase enzyme *in vitro*, demonstrating a much greater affinity for the purified enzyme than its natural substrate citrate as well as the other stereoisomers of hydroxycitric acid (1-2). The biological importance of ATP citrate lyase is as a citrate cleavage enzyme which catalyzes the extramitochondrial cleavage of citrate to acetyl CoA and oxaloacetate, and facilitates the biosynthesis of fatty acids. The reversible inhibition of citrate lyase by (-)HCA may lead to the reduction of fatty acids synthesis and lipogenesis. These effects have been measured and demonstrated *in vivo* following the oral, *iv* or *ip* administration of (-)hydroxycitrate to experimental animals (3). When (-)HCA was given orally before the feeding period, the animals fed (-)HCA consumed less food and their hepatic synthesis of fatty acids and cholesterol was significantly diminished as compared to the untreated controls (3-4). The observed decrease in food intake may be only one of the factors responsible for the (-)HCA promoted weight loss, because experimentation with rats fed (-)HCA showed weight loss with no decrease in cumulative food intake (5). It seems that the potential mechanism of weight loss with (-)HCA may include an energy expenditure component, the nature of which remains undetermined (5). This mechanism of energy expenditure, decreased lipogenesis, and the reduction in food intake in the (-)HCA receiving animals may result in weight and total body fat content loss in experimental animals (6).

Although the potential of (-)HCA as a weight lowering compound has been recognized since the 1970's, only few clinical studies have been conducted with this compound (7-12). The purpose of our study was to evaluate the weight loss properties of the (-)HCA formula in a population of young to elderly overweight individuals supplemented daily for a period of eight weeks.



K_m (citrate)	0.057 ± 0.007
V_{max}	0.030 ± 0.001
K_i	0.008 ± 0.001
K_i / K_m	0.14

Figure 1 - (-)-Hydroxycitric acid and its pharmacokinetic characteristics (1)

MATERIALS AND METHODS

Patients

Overweight subjects of both genders with a body mass index (BMI) of >25 kg/m² and

<45 kg/m^2 were eligible for the study. Pregnancy, lactation, use of appetite suppressants on a regular basis, history of alcohol or other drug abuse, and allergies to spices or any of the study products were the exclusion criteria from the study group. Medical conditions which were longstanding and managed on an outpatient basis with either OTC or prescription drugs were not exclusion criteria.

Patients were recruited through advertisements in a local newspaper. After being interviewed to find out whether they met the inclusion criteria for the study, the subjects received verbal information about the aim of the study and the nature of the botanical compound they would be required to take daily. Subsequent to the successful interview, all selected participants were asked to sign an informed consent form. A total of 77 ambulatory patients were admitted to the study group.

Evaluated Formula

The tested formula, in the form of tablets, contained (-)hydroxycitric acid, a compound extracted from the rind of the *Garcinia cambogia* fruit (fam. Clusiaceae). Each tablet consisted of 500 mg of the calcium salt of (-)hydroxycitric acid and 100 mcg of elemental chromium in the form of chromium picolinate. Each tablet provided 250 mg of pure (-)hydroxycitric acid (50% hydroxycitric acid by HPLC analysis). The Citrin® brand of (-)hydroxycitric acid was provided by Sabinsa Corporation, New Jersey, USA. The composition of Citrin® powder was as follows: (-)hydroxycitric acid >50%, calcium >19%, water approx. 5%, organic matter of plant origin approximately 22%, and inorganic matter of plant origin approx. 4%. The composition of chromium picolinate used in the study was as follows: picolinic acid - 82.5%, elemental chromium - 12.5%, and water approximately 5%.

Study Protocol

The eight-week open field study was designed to evaluate the weight loss properties of the botanical formula based on a daily intake of 750 mg of (-)HCA and 300 mcg of elemental chromium. The protocol required one tablet of the (-)HCA formula be taken three times daily, 30 minutes before a meal. Each patient was provided with a supply of tablets on a weekly basis. Compliance with the regimen was assessed at weekly clinical visits, using the number of returned test medications as an indication of compliance.

All subjects were given the same dietary instructions and were told to continue their usual physical activity. No effort was made to enforce a more strenuous or frequent exercise program. The dietary instructions were reviewed with the subjects in a similar manner; emphasis was placed on the values of the Smart Choices diet: low-fat, low-sugar, low-sodium, rich in vegetables and fruits, variety, moderation, and balance. All subjects were encouraged to drink 64 oz. of water a day for its beneficial effects. Body weight, vital signs, self assessment of appetite and daily performance or energy parameters were taken in a physician's office at the onset of the study, at week four, and week eight (conclusion of the study). Levels of appetite were evaluated based on the following scale: 0 - not hungry; 1 - somewhat hungry; 2 - very hungry; 3 - extremely hungry. Energy levels were evaluated based on the following scale: 0 - very tired; 1 - somewhat tired; 2 - some energy; 3 - lots of energy. The clinical biochemistry of the participants was evaluated prior to the treatment and after eight weeks of regular (-)HCA formula intake. The study was performed in a Bariatric Clinic at Hilton Head, SC and supervised by a bariatrician with over 30 years of experience in the field.

Statistical Analysis

The clinical parameters obtained at the inception, after four weeks and after eight weeks of the study were statistically evaluated. Biochemical data obtained prior to the study and at its completion, eight weeks later, were statistically evaluated. The gender groups and age groups, group (1) ages 20 to 40, (2) ages 41 to 50, and (3) ages 51 to 64 were statistically evaluated. Descriptive statistics of the groups were determined; mean values and 95% confidence intervals (CI) were calculated. Statistical analysis was performed using runs test (examining randomness of the sample) and the Shapiro-Wilk test (assessing departure from normality). The significance of difference between groups was evaluated with the use of a parametric test, namely the paired *t-test*. In order to avoid erroneous rejection of the null hypotheses, the results of this evaluation were confirmed by a less powerful test, known as the Wilcoxon matched-pairs signed-rank test, a non-parametric test which evaluates the significance of difference for dependent samples. In our studies, matching was used to control potentially confounding variables and to increase power and precision of estimates by decreasing the width of the confidence interval estimate of the population parameter. Confidence intervals were evaluated to provide a range within which the true population parameter was likely to fall.

Results

Seventy-seven overweight individuals, 15 men and 62 women, were selected for the study. Of this group a woman who was at that time on anti-hypertensive and hormonal replacement regimens declined participation as advised by her primary care physician. Two other patients, a man and a woman, were lost to follow-up within the first week. Of the remaining 74 participants, one man and 18 women dropped-out of the program, i.e. 11 drop-outs (58%) after two weeks, 3 drop-outs (16%) after four weeks, and 5 drop-outs (26%) after six weeks. Those who dropped-out were lost to follow-up (10 drop-outs (52%)) or non-compliance with the program (8 drop-outs (43%)). One person (5%) quit the program as a result of mental depression. There were no significant differences in age, body weight or BMI between subjects who withdrew from the study and those who completed the eight-week program. None of the subjects who did not complete the program reported any side effects of the therapy.

Of the 55 participants who completed the eight-week regimen, thirteen were men and fourty-two women. This population included 17 individuals age 20-40 years old, 16 age 41-50 years old and 22 age 51-64 years old. Of those who completed the protocol, 13 (23%) did not have concurrent health problems, while 42 (76%) reported medical conditions for which OTC and/or prescription treatments were taken while on the program. Of the 42 participating women, 13 (30%) were on estrogen replacement therapy, 7 (12%) had cardiovascular disease, 9 (16%)

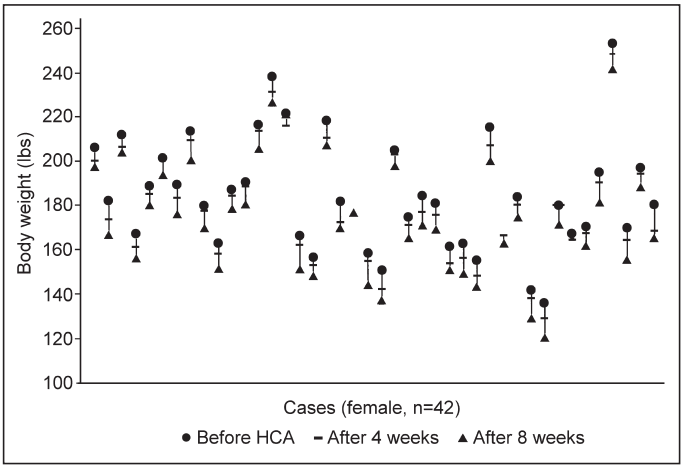


Figure 2 – Effect of 4 and 8 weeks administration of (-)HCA formula on body weight in women (p<0.001)

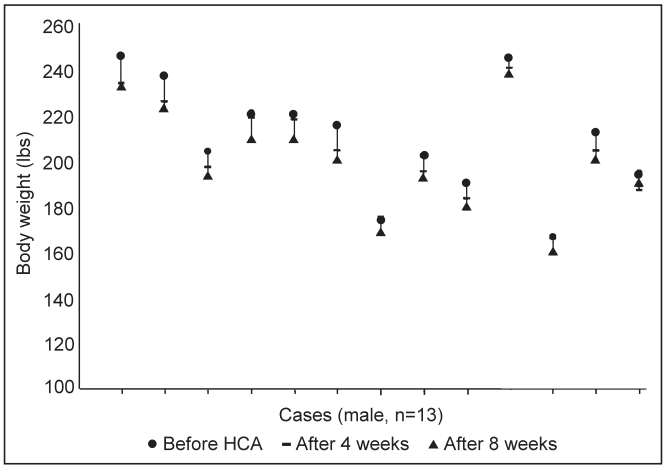


Figure 3 - Effect of 4 and 8 weeks administration of (-)HCA formula on body weight in men (p<0.001)

presented with hypothyroidism, 2 (4%) presented diabetes type II, 2 (4%) had depressive illness, 12 (22%) were on NSAID and OTC pain relieving drugs for musculo-skeletal pain and headaches, and 7 (12%) were taking oral antibiotics for upper respiratory, urinary and skin infections. Four (10%) women were on birth control pills prior to and during the study. Those participants who were taking OTC or prescription drugs for preexisting medical conditions did not report any incompatibility reactions or deterioration of their health during the course of the study.

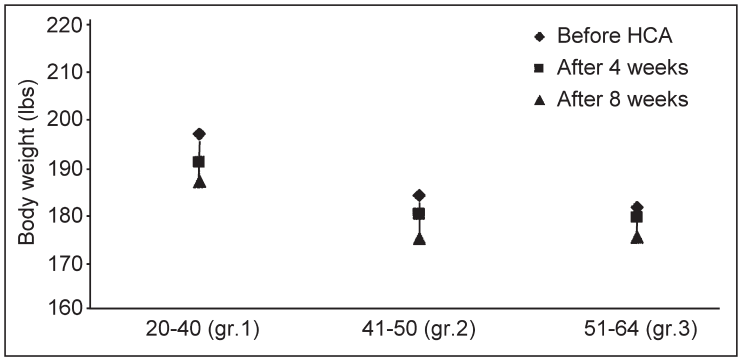
CLINICAL PARAMETERS BEFORE AND AFTER FOUR AND EIGHT WEEKS OF THE (-)HCA REGIMEN

Body Weight

There was a significant decrease in body weight after four weeks ($p<0.001$) and after eight weeks ($p<0.001$) of (-)HCA formula intake for the entire sample (Figures 2 and 3). The mean weight loss values for women after four weeks and after eight weeks were 4.4 (CI: 3.5-5.4) lbs. and 9.5 (CI: 8.2-10.9) lbs., respectively. The corresponding weight loss values for the men after 4 weeks and eight weeks were 6.1 (CI: 3.6-8.5) lbs. and 10.4 (CI: 8.5-12.3) lbs., respectively.

The body weight parameter evaluated in the three age groups followed the total population and gender groups trend, showing significant ($p<0.001$) weight loss after four weeks and after eight weeks of (-)HCA formula intake (Figure 4). The mean weight loss values after four weeks and eight weeks of treatment were as follows: group 1 - 5.5 (CI: 3.9-7.2) lbs. and 9.2 (CI: 7.2-11.3) lbs.; group 2 - 3.9 (CI: 2.1-5.8) lbs., 8.7 (CI: 6.1-11.3) lbs.; group 3 - 4.7 (CI: 3.3-6.2) and 10.9 (CI: 9.6-12.2) lbs.. For the entire population examined, the mean weight loss after four weeks and eight weeks of (-)HCA formula administration was 4.8 (CI: 3.9-5.7) lbs. and 9.7 (CI: 8.6-10.8) lbs., respectively. The body weight loss during the eight-week administration of the (-)HCA formula correlated well with the length of regimen (Figures 5 and 6).

Figure 4 - Effect of 4 and 8 weeks administration of (-)HCA formula on body weight in different age groups (p<0.001)



Appetite and Energy

Analysis of the subjective perception of appetite and energy levels, as assessed in the entire sample studied, showed a significant ($p<0.01$) decrease in cravings for food and a significant ($p<0.01$) increase in energy levels in the four week and eight week self-evaluation scores (Figure 7). Diminished appetite perception and elevated vitality, were observed in both men and women. The reported loss of craving for food occurred in a matter of weeks after implementation of the treatment. The lowest levels were reported after four weeks of formula intake and leveled off in the remaining four weeks.

Vital Signs

The vital signs, i.e. pulse rate, systolic and diastolic blood pressure values, were evaluated in all patients before and after four and eight weeks of (-)HCA formula intake. This evaluation showed a trend in lowering systolic blood pressure during the course of treatment for the entire sample studied; however the differences before and after treatment were not statistically significant.

BLOOD CHEMISTRY BEFORE AND AFTER EIGHT WEEKS ON THE (-)HCA FORMULA

Blood Lipids and Glucose

Blood lipids and glucose levels evaluated before and after the eight-week administration of the formula showed significantly changed levels of blood lipids (Table I). The following pattern was recorded: decrease in triglycerides, decrease in very low-density lipoproteins (VLDL), decrease in low density lipoproteins (LDL) and an increase in high density lipoproteins (HDL). The levels of total blood cholesterol were not affected by the treatment.

The blood levels of triglycerides assessed for the entire population decreased significantly ($p<0.05$). The mean value of triglyceride levels was 167 (CI: 140-191) mg/dl before the (-)HCA formula intake and 155 (CI: 130-180) mg/dl after eight weeks of the regimen. The mean value of triglycerides in men at the start was 216 (CI: 154-278) mg/dl and 205 mg/dl after eight weeks of treatment. This decrease in the triglyceride levels was significant ($p<0.05$). In women, the decrease in triglyceride levels was also significant ($p<0.05$) (mean value before treatment 151 (CI: 122-180) mg/dl and mean value after treatment 138 (CL:

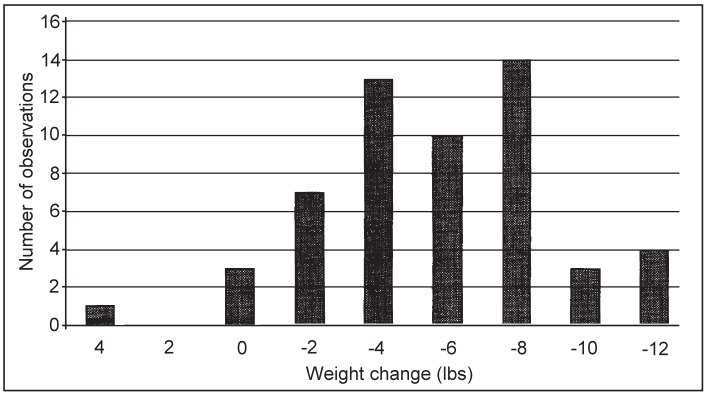


Figure 5 – Distribution of weight change (lbs) after 4 weeks of (-)HCA formula administration in the entire population studied

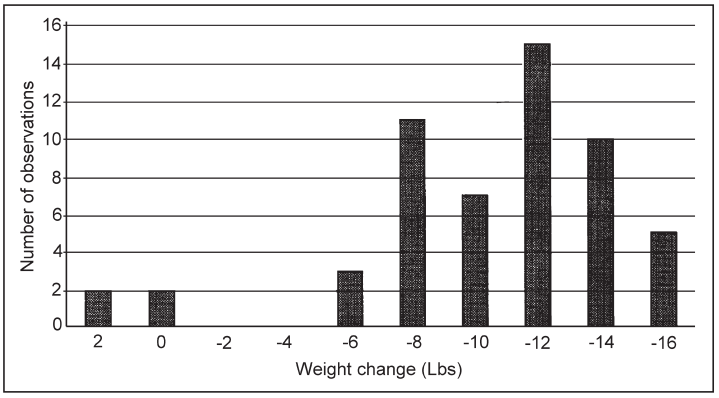


Figure 6 - Distribution of weight change (lbs) after 8 weeks of (-)HCA formula administration in the entire population studied

112-164) mg/dl). The changes in triglyceride levels for all age groups followed the general trend, but were not statistically significant.

VLDL were significantly ($p<0.05$) lowered only in one population studied, age group 3 (51 to 64 years of age). The levels of VLDL in this group decreased from a mean value of 34 (CI: 24-44) mg/dl before treatment to a mean value of 29 (CI: 21-36) mg/dl after eight weeks of treatment.

LDL were significantly ($p<0.05$) lowered only in one population studied, age group 1 (20 to 40 years of age). The levels of LDL in this group decreased from a mean value of 124 (CI: 107-141) mg/dl before treatment to a mean value of 116 (CI: 101-131) mg/dl after the treatment.

HDL were significantly ($p<0.01$) increased in all groups combined after eight weeks of the (-)HCA formula treatment (mean value before treatment = 47 (CI: 43-51) mg/dl, mean value after treatment 50 (CI: 41-59) mg/dl). The HDL increase was not significant for men, but it was significant ($p<0.01$) for women. The mean values of HDL in women before treatment and after treatment were 50 (CI: 42-58) mg/dl and 53 (CI: 41-65) mg/dl, respectively. HDL increased significantly ($p<0.01$) in only one of the age groups, group 1 (20-40 years of age). The mean value of HDL in group 1 before treatment was 47 (CI: 39-56) mg/dl and 51(CI: 42-60) mg/dl after treatment.

Blood glucose levels showed a trend towards decrease in all populations studied during the eight-week treatment. This change, however, was not statistically significant.

Coronary Heart Disease (CHD) Risk Factor

Cardiovascular risk or Coronary Heart Disease (CHD) risk based on the total cholesterol/HDL ratio was evaluated before and after the eight-week treatment (Table I). The eight week intake of the formula lowered CHD risk significantly ($p<0.01$) for the entire sample studied, decreasing the risk index from a mean value of 0.99 (CI: 0.87-1.13) to a mean of 0.90 (CI: 0.76-1.04). The CHD risk was significantly ($p<0.01$) lowered in men after the treatment. The mean value of the risk index decreased from 1.26 (CI: 1.05-1.46) to 1.04 (CI: 0.73-1.35). Although the CHD risk declined for women from 0.91 (CI: 0.77-1.05) to 0.84 (CI: 0.68-1), the change was not statistically significant. Coronary Heart Disease risk declined in all age groups, but significantly ($p<0.01$) in the group of 51-64 years old.

DISCUSSION

The weight loss results with the (-)HCA formula treatment could be explained, to some degree, by the fact that most of the patients ate less due to decreased cravings for food. The appetite lowering effect of the treatment had a tendency, however, to diminish after the initial four weeks while patients continued to lose weight. This discrepancy may indicate that a mechanism independent of food intake is responsible and results in weight reduction with administration of the (-)HCA formula.

The blood chemistry data indicate that the (-)HCA formula may be involved in lipid metabolism. The significantly ($p<0.01$) lower levels of blood triglycerides as a result of the eight week treatment may indicate that the (-)HCA formula decreases production of fatty acids and/or increases the metabolic utilization of fatty acids (Table I).

In our study, each patient was asked to report on his or her energy levels, through a questionnaire, during the course of their eight-week treatment. Analysis of the subjective perception of energy levels showed a significant ($p<0.01$) increase in energy after four weeks and eight weeks compared to the energy levels at the onset of the study. These subjective observations of increased energy levels should be further studied since they may reflect, or be a result of, increased levels of glycogen stores in the body. (13) The sufficient glycogen stores in the body may be one of the factors responsible not only for the increased energy levels in patients receiving (-)HCA, but also for the satiety mechanism. (13)

An added benefit of the (-)HCA regimen seems to be a decrease in the cardiovascular risk index as calculated from the blood lipid profile. Our experience indicates that even a relatively short, eight week, regimen involving the (-)HCA formula significantly diminished the blood lipid calculated cardiovascular disease (CHD) risk index. This health benefit, combined with a lowering of body weight, is of particular importance since body weight and the CHD risk index are well recognized predictors of the overall morbidity and mortality rate.

The safety of any weight-loss regimen is a paramount issue. In addition to evaluating clinical and biochemical safety parameters for the continuous use of (-)HCA in the eight-week study, we also evaluated the same parameters in an eight-month up to 36 month program (Badmaev, V. Majeed, M., Anthony Conte - personal communication 1995). In short and long term studies the (-)HCA formula did not produce any objective and subjective side effects. Also, the therapy did not affect the vital signs of treated individuals, i.e. the heart rate and blood pressure parameters. Blood chemistry data obtained prior to the (-)HCA formula regimen, after eight weeks and up to three years of the continuous regimen, indicate that no significant difference in any biochemical parameters related to the function of major organs or systems in the body occurred. Patients for the long-term study were recruited from the same pool of ambulatory patients who participated in the short-term study. The overweight subjects evaluated long term were 12 women and one man, 33 to 76 years old, and were carefully selected to comply with the guidelines of the long term study.

Table I - Blood lipid profile after 8 weeks of treatment with (-)HCA formula

	Triglycerides [1]	VLDL [2]	LDL [3]	HDL [1]	Cardiovascular Risk Factor [1]
Mean Baseline Value (CI)	167 mg/dL (140-191)	34 mg/dL (24-44)	124 mg/dL (107-141)	47 mg/dL (43-51)	0.99 (0.87-1.13)
Mean 8 Week Value (CI)	155 mg/dL (130-180)	29 mg/dL (21-36)	116 mg/dL (101-131)	50 mg/dL (41-59)	0.90 (0.76-1.04)

1. Significant change ($p<0.05$) between baseline and 8 week values in entire population
2. Significant change ($p<0.05$) in age group (3) 51-64 years
3. Significant change ($p<0.05$) in age group (1) 20-40 years

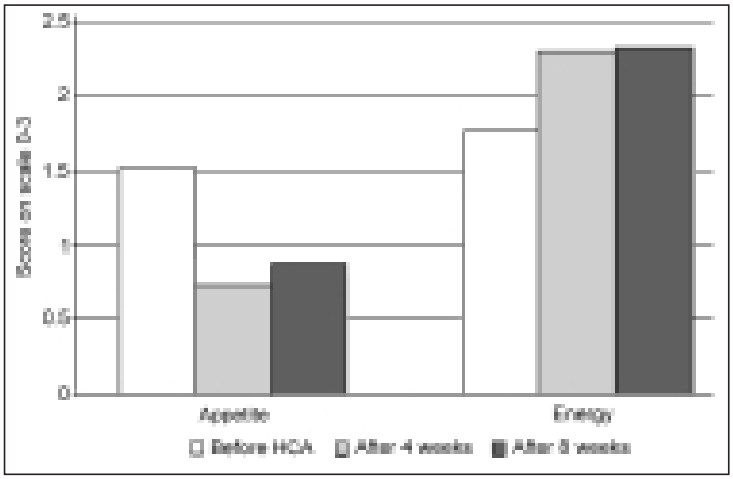


Figure 7 - Levels of appetite and energy in the entire population studied receiving (-)HCA formula for 4 and 8 weeks

The several month intake of the (-)HCA formula also resulted in a significant ($p<0.05$) weight reduction from a mean value of 158 (CI: 139-177) lbs. to a mean value of 146 lbs. The blood lipid profile evaluated before and after the long-term treatment showed a pattern similar to that seen in the eight-week study, however numerical changes were not statistically significant. On the other hand, the mean value for CHD risk index in the studied population was 0.94 before and 0.87 after the treatment, and this change was statistically significant ($p<0.05$).

In the long-term study, most participants had health problems. Twelve of the 13 long term patients had preexisting medical conditions, i.e. dyslipidemia (5/13), essential hypertension (3/13), hormonal imbalance (3/13), mental depression (2/13), Crohn's disease (1/13), hypothyroidism (1/13), epilepsy (Petit mal) (1/13), osteoarthritis (1/13), allergic sinusitis (1/13), reflux esophagitis (1/13), and gout (1/13). The patients received the following prescription medications concomitant with the administration of the (-)HCA formula: Inderal, Lotensin, Questram, hydrochlorotiazide, Estraderm patch, Prozac, Librium, Prilosec, Zantac, Tavist D, Benemid, Prinivil, allopurinol, Motrin, Depakote, Tegretol, Neurontin. During the eight week and up to three years of continuous intake of the (-)HCA formula, no side effects nor drug incompatibility were reported by the patients or their supervising physician.

The (-)HCA formula evaluated in the study consisted of two ingredients which, based on literature data, may have additive effects on weight loss: (-)hydroxycitric acid and chromium. An evaluation of chromium plasma levels before and after the eight-week regimen revealed that at the baseline only three subjects had detectable levels of chromium (0.8 to 2.3 mg/L). However, after eight weeks of formula administration, plasma levels of the studied population showed a diametrically different pattern with only two individuals presenting undetectable levels of plasma chromium. The remaining population had plasma chromium levels after the study ranging between 0.8 to 4.8 mg/L.

The (-)HCA formula was designed to provide a primary acting ingredient, (-)hydroxycitric acid, with an adjuvant dose of chromium supplementation. The benefits of trivalent chromium, an essential trace element, for weight loss have been previously described. (14) However, there is no consensus on the efficacy of chromium in weight loss and its supplemental dose. (14-17)

Our positive clinical and biochemical findings in the absence of side effects in the overweight individuals receiving the (-)HCA formula indicate the potential of this approach in the treatment of obesity. Future evaluation of the weight-loss potential of (-)HCA should include studying the blood and tissue bioavailability of this compound, especially since the mechanism of (-)HCA depends on its presence in the cell cytoplasm where it inhibits the ATP citrate lyase enzyme.

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