

The Effects of an Eight Week Weight Loss Program in Obese Adults Utilizing a Nutritional Supplement

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Abstract: A non-placebo controlled, blinded study utilizing a commercially available meal replacement (manufactured by Nutrition Laboratories Inc., Florida) studied 35 adult participants to determine the safety and efficacy of the product (a liquid nutrient concentrate) while measuring weight reduction, lipids, and adipose tissue, liver enzymes and metabolic indices (glucose, cholesterol and triglycerides) over an eight-week period. The average weight loss after 14 days was 18.2 (\pm 3.7) pounds and 28.4 (\pm 6.5) pounds at the conclusion of the eight-week trial. This was found to be statistically significant ($p < .01$). Patient's metabolic functions were closely monitored in order to document therapeutic benefit, while monitoring for potential side effects. Total cholesterol was lowered in all participants (ave. reduction = 20.6 mg/dL) and every participant with clinically elevated cholesterol (≥ 200) at baseline, reported normal values after eight-weeks. Similarly, all participants with fasting hyperglycemia (s. glu. ≥ 100) returned to normal by the end of the study. This included three patients with NIDDM who were not well controlled prior to the study. There was no evidence of hypoglycemia (s. glu. ≤ 65). Participants with elevated liver enzymes at baseline reported normal SGOT & SGPT levels after two-weeks. No participant developed liver enzyme elevations. Subjective energy level of the participants was reported at baseline as low to average and reported as high to very high at the conclusion of the study. All participants lost total adipose tissue with the average change calculated at a 6.7% loss.

Keywords: Metabolic syndrome, insulin resistance, type II diabetes mellitus, obesity, atherosclerosis, hyperlipidemia.

INTRODUCTION

Obesity is the number one contributor to the development of metabolic syndrome (obesity, diabetes mellitus, heart disease and atherosclerosis) in developed countries [1]. The toll, due to obesity, both medically and economically is huge [2]. While genetic factors contributing to obesity, hyperlipidemia and diabetes cannot be changed, we can successfully address the exogenous contribution to these disease states. Pharmaceutical attempts to promote weight loss have historically been accomplished via drastic surgical means [3] and appetite suppressants that many times are addictive [4, 5] and or have cardiovascular side effects [6-9]. The prescribing patterns of these medications are closely monitored by the board of pharmacy in most states, due to abuse [10] and misuse by patients and prescribers. This study was conducted to document scientifically an effective and safe product to help obese individuals lose weight. The individual components of the nutritional supplement have been studied for safety and effectiveness. The purpose of this study was to evaluate the effectiveness and safety of this proprietary blend [11] as an aid to weight loss. The results of this study bear out that there are safe, effective adjuncts to weight loss without the need for prescription medication or frequent physician visits.

METHODS

Inclusion in the study required that all subjects were obese adults, between the age 18 and 65, whose weight was at least 30% over IBW (ideal body weight – see example**). IBW for males was calculated utilizing the formula: 106# for the first 60" of height and 6# for each additional inch, plus or minus 6#s. Females utilize the formula: 100# for the first 60" and 5# for each additional inch, plus or minus 5#s. The study sample consisted of 35 qualified and consented subjects, 27 females and 8 males. The average percentage over IBW was 36% (range of 30% - 45%). All participants received a general physical exam, anthropological body measurements utilizing the Jackson – Pollock scale. This included weight, body circumference measurements of arms, abdomen, hips and thighs plus body fat analysis with caliper measurements of arms, sacroiliac and thigh in females and chest, abdomen and thigh in males. Laboratory analysis included comprehensive metabolic panel + lipids at baseline visit and upon conclusion of the study (day 56). On the first visit, the participants were started on a bowel cleanser which consisted of 3 tablets of senna (100mg) and given the study products (see list of ***ingredients) and protocol for days 1-56. They returned on day 3 to discuss the results of baseline laboratory. Participants were offered the opportunity to return on day 14 for a re-weight and follow up lab if they were clinically indicated. On day 56, all participants were seen for a follow up visit. Weight, body measurements and labs

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were repeated. The primary ingredients, by volume, include *Opuntia ficus-indica* [12-14], *Aloe barbadensis miller* [15, 16], *Silybum marianum* [17], however a complete list of active elements are located below ***.

****IBW Examples:** a male 5' 8" (68") would have an IBW of 148-160. A female of 5'8" (68") would have an IBW of 135-145. Study participants would be equal or greater than 30% more than the upper limit of the IBW range. The male in the above example would have to weigh ≥ 208 (30% greater than 160) and the female would have to weigh ≥ 188 (30% greater than 145).

Statistical Analysis

Student t-test was carried out on each variable to determine if there was a significant difference between the mean of the initial measurements, (baseline) and the mean of the subsequent measurements (post-study). All results rejected a null hypothesis and were significantly different, ($p < 0.05$). The Pearson coefficient was calculated to test the degree of correlation in the change detected between the pre and post-treatments. All results showed a significant coefficient ($r = .82$, 67.24 %) consistent with the change observed clinically.

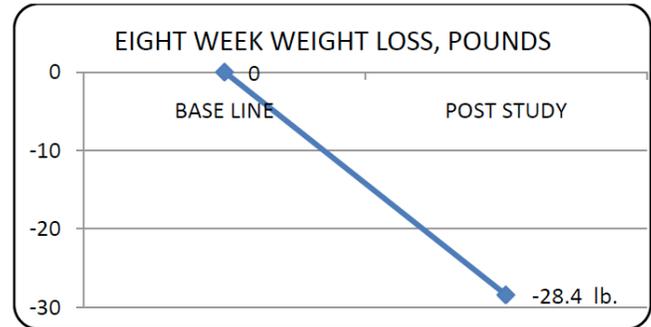
RESULTS

All measurements reported on the 35 subjects were recorded twice during the study (at randomization [day #1] and at the conclusion of the study, [day #56]). A large portion of the participants ($n=27$) voluntarily presented at day 14 to evaluate short term weight loss. The average weight loss after 14 days was 18.2 (± 3.7) pounds. Statistical analysis of the two week weight loss was not performed and was considered anecdotal. It is mentioned here to note that there were short term and long term effects to the nutritional supplement. All subjects served as their own controls.

Total Body Weight

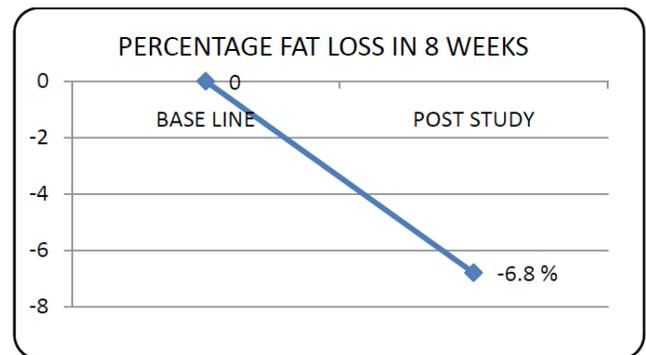
Every subject in the program lost weight. Weight loss due to bowel catharsis was an average of 2.7 (± 1.3). This weight loss was discarded when evaluating the total weight loss, as it was considered fecal matter and not loss of fat mass. All participants continued to utilize the nutritional supplement program to replace one meal per day for a total of 56 days. The average

weight loss after 14 days was 18.2 (± 3.7) pounds and 28.4 (± 6.5) pounds at the conclusion of the 8 week trial. The eight week weight loss was found to be statistically significant ($p < .01$).



Adipose Tissue

The average percentage loss of adipose tissue was 6.8% (± 0.8), ($p < 0.05$).



Metabolic Indices

Glucose: The average serum glucose at baseline was 93.76 mg/dL ± 1.89 . Glucose at day 14 was 89.55 (± 1.80) and 92 (± 1.54) at the conclusion of eight weeks. These numbers were not statistically significant. Three participants with clinically significant hyperglycemia (fasting glucose ≥ 100) had normal values at the conclusion of the study. Of these three subjects, the baseline fasting glucose was 154.33 (± 22.67 mg/dL). These three subjects fasting glucose on day 42 was 94 (± 2.33 mg/dL). Hgb A_{1c} was not obtained. These findings were not statistically significant, however, clinically very revealing.

Total Cholesterol

The average loss of total cholesterol was 20.6 mg/dL (± 6.23). The total cholesterol at baseline was 192.2 mg/dL (± 8.05) and at day 42, was 171.6 mg/dL (± 5.67), ($p < 0.05$).

Triglycerides

The average loss in triglycerides was 18.3 mg/dL (± 4.22) for 34 of the 35 patients, ($p < 0.05$).

Of particular interest was one participant whose baseline triglyceride was 1430 mg/dL (normal ≤ 149 mg/dL). The subject was notified of the "critical" values and was offered to be more closely monitored and to be referred to an independent physician for further evaluation. He initially chose to remain in the study. At day 14 his triglyceride level was reduced to 894 mg/dL, at day 28 was reduced to 782 mg/dL and at day 42 was reduced to 593 mg/dL. He experienced a reduction of 837 mg/dL of his triglycerides. This outlier is clinically interesting, although not considered a statistically significant. His data was excluded from the statistical analysis, as he was lost to follow-up. Upon conclusion of the study, he was advised to follow-up (via certified mail) with a physician.

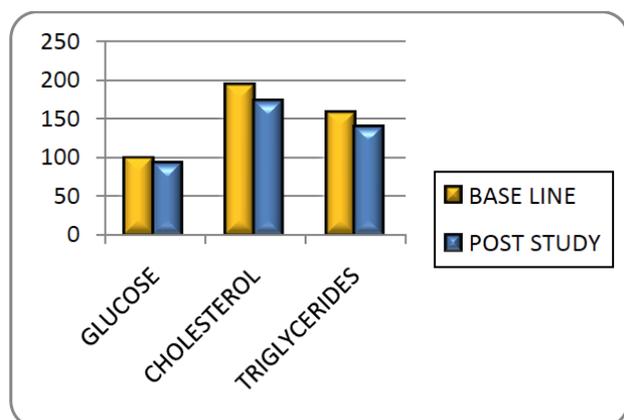


Figure 1: Metabolic indices, mg/dl.

DISCUSSION

This study was a blinded, clinical trial in which subjects served as their own control for a period of 8 weeks (56 days). The primary end points of the study were to document the efficacy of a non-pharmacological weight loss system while monitoring for safety. Secondary end points were to demonstrate if the studied products would improve the components of metabolic syndrome. This is accomplished by reducing fasting glucose, cholesterol and triglycerides while monitoring hepatic and renal functions for safety.

Each subject was monitored for changes in total body weight, percentage of adipose tissue (total body fat), waist, hips, chest measurements as well as glucose, SGOT, SGPT, albumin, total cholesterol and triglycerides.

Significant reductions were found in total weight loss, total body adipose tissue, cholesterol and triglycerides while participants experienced no clinically significant adverse effects. There were no elevations in hepatic function studies and participants experienced normalization in SGOT, SGPT if those values were elevated at baseline. Likewise, there were three participants with elevated fasting glucose at baseline. These three participants had normalization of their fasting glucose upon conclusion of the study, while there were no subjects who experienced hypoglycemia. All subjects reported stable serum albumin levels as documentation maintenance of proper nutritional balance.

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Dr. Lane is the Scientific Director of Metabolic and Genetic Research Institute: Largo, Florida. He is a graduate of Ohio University College of Osteopathic Medicine, Athens, Ohio and Past Associate Medical Director for Hilltop Research and Radiant Research, Columbus Ohio. Past Associate Professor of Medicine, Ohio University, College of Osteopathic Medicine, Dept of Family Medicine & Geriatrics, Athens, Ohio.

Dr. Lane reports no financial affiliation with Nutrition Laboratories Inc., Florida

Ingredients

Opuntia ficus-indica [11-13], Aloe barbadensis miller [14, 15], Silybum marianum [16], Eleutherococcus senticosus [18, 19], Panax quinquefolius [20], Camellia sinensis [21], Rhodiola rosea [22], Schisandra Chinensis [23], Pfaffia paniculata [24], Ilex paraguariensis [25], Tabebuia avellanedae [26], Garcinia cambogia [27], Gymnema sylvestre [28], Foeniculum vulgare [29], Arctium minus [30], Mentha peperita [31], Ulmus rubra [32], Glycyrrhiza glabra [33], vitamins A, D3, C, B1, B2, B3, B5, B12, folic acid, biotin, choline, calcium, magnesium, potassium, chromium, arginine, carnitine, glutamine, isoleucine, leucine, methionine, phenylalanine, threonine, tryptophan, tyrosine, valine.

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