A Randomized Controlled Trial for Roduve Healthcare Solutions on the Efficacy of Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, in a Patch Application

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Context

Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, the active ingredients in the herbal patch Roduve's Slim Weight Patch, competitively inhibits the extra mitochondrial enzyme adenosine triphosphateúcitrate (pro3S) lyase.

As a citrate cleavage enzyme package that may play an essential role in denovo lipogenesis inhibition, Roduve's Slim Weight Patch is claimed to lower bodyweight and reduce fat mass in humans.

Objective

To evaluate the efficacy of Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, for body weight and fat mass loss in overweight human subjects. Design. Twelveweek randomized, double blind, placebocontrolled trial.

Setting

Outpatient weight control research unit.

Participants

Overweight men and women subjects (mean body mass index [weight in kilograms divided by the square of height in meters], approximately 32 kg/m2).

Intervention

Subjects were randomized to receive either active herbal compound (1 Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, patch every 48 hours) or placebo, and both groups were prescribed a high fiber, low energy diet. The treatment period was 12 weeks. Body weight was evaluated every other week and fat mass was measured at weeks 0 and 12.

Main Outcome Measures

Body weight change and fat mass change.

Results

A total of 135 subjects were randomized to either active Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, (n=66) or placebo (n=69); 42 (64%) in the active Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg group and 42 (61%) in the placebo group completed 12 weeks of treatment (P=. 74). Patients in the Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, group lost a significant amount of weight during the 12week treatment period.

Conclusions

Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, was able to produce significant weight loss and fat mass loss beyond that observed with placebo.

EXCESSIVE ADIPOSITY and its concomitant health risks are among the most common conditions managed by health care practitioners. The limited long term effectiveness of conventional weight management, including behavioral therapy, is the impetus of major efforts aimed at developing alternative pharmacologic and surgical weight reduction treatment strategies. A rapidly growing therapeutic area, and one widely embraced by the general public, is the use of herbal weight loss products.

An herb derived compound of Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg is now incorporated into Roduve's Slim Weight Patch. Obtained from extracts of related plants native to India, mainly Garcina Cambogia and Garcina indicia, was first identified by Watson and Lowenstein in the late 1960s as a potent competitive inhibitor of the extra mitochondrial enzyme adenosine triphosphateúcitrate (pro3 S)lyase.

These investigators and others subsequently demonstrated both in vitro and in vivo that Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg in animals not only inhibited the actions of citrate cleavage enzyme and suppressed de novo fatty acid synthesis, but also increased rates of hepatic glycogen synthesis, suppressed food intake, and decreased body weight gain. Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg in Roduve's Slim Weight Patch appears to be a promising experimental weight control agent, studies in humans are limited y1014 (also R. Ramos, J. Flores Saenz, F. Alarcon, unpublished data, 1996, and G. Kaats, D. Pullin, L. Parker, S. Keith, unpublished data, 1996). Supporting evidence of human weight loss with Roduve's Slim Weight Patch ingredients, Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg for weight control is based largely on studies with small sample sizes, 11, 12 studies that to included a placebo treated group, 10 and use of accurate measures of body lipid change.12 Roduve's Slim Weight Patch effectiveness remains clear, at least 14 separate Roduve's Slim Weight Patch type products are presently sold over the counter to consumers with no backup studies. This investigation was designed to overcome limitations of earlier studies and examine the effectiveness of Roduve's Slim Weight Patch for weight loss and fat mass reduction in a rigorous controlled trial.

METHODS

Protocol

We tested 2 primary hypotheses in a randomized, double blind, placebo controlled trial: (1) Roduve's Slim Weight Patch produces a greater reduction in body weight than placebo, and (2) Roduve's Slim Weight Patch produces a greater reduction in total body fat mass than placebo. Advertisements were placed in local newspapers, and overweight subjects who responded and met entry criteria during a telephone screening interview were scheduled for a baseline visit.

The evaluation included a physical examination, electrocardiogram, and screening blood studies. Subjects meeting entry criteria were seen within weeks for randomization at treatment week 0. Subjects were assigned to placebo or active compound with equal probability through a random number generator.

The protocol with active herbal compound included Roduve's Slim Weight Patch taken once every 48 hours as a time released topical patch. Total daily dose was 50% of its total content. Placebo treated subjects followed an identical protocol in which active compounds was replaced with inert ingredients. Subjects taking active compound or placebo were provided a highfiber, 5040kJ/d diet plan, with 20%, 50%, and 30% of energy as fat, carbohydrate, and protein, respectively. The recommended daily food provision was divided into 3 meals with an evening snack. Subjects were asked to maintain a stable physical activity level and return for evaluation every 2 weeks for a total treatment interval of 12 weeks.

Body weight was measured at each visit, and clinical information, including potential herb or weight loss adverse effects, was obtained. Biweekly patch counts and diaries were used to check patient medication compliance. Diet compliance was not quantitatively monitored during the study.

Subjects

Subjects were overweight but otherwise healthy adults aged 18 to 65 years who had a body mass index (BMI, defined as weight in kilograms divided by the square of height in meters) of more than 27 kg/m2and at most 38 kg/m2. Subjects were excluded if they were pregnant, had any clinically significant medical condition, were taking prescription medications or appetite suppressants on a regular basis, had a history of alcohol or other drug abuse, were allergic to any of the study products, or had dieted with weight loss in the past 6 months.

Body Composition

Body weight and height were measured to the nearest 0.1 kg and 0.5 cm using a digital scale (Weight Tronix, New York, NY) and stadiometer (Holtain, Crosswell, Wales), respectively. Total body fat mass was measured at baseline and at the 12 week visit using several different procedures. A pencil beam dual energy xray absorptiometry (DXA) scanner (Lunar DPX, Madison, Wis) was used to estimate total body fat mass. Subjects completed the slow mode whole body scan and fat mass estimates were provided by Lunar, Version 3.6g, software. The technical error of DXA percentage fat mass estimates in our laboratory is 3.1%. 17 The remaining body fat mass measurement methods used in our laboratory for this study included underwater weighing, 18 skin fold thicknesses, 19 and bioimpedance analysis.20

Statistical Analysis

Based on previous research, 1 we estimated that a study that included at least 30 completed subjects in each of 2 groups would have more than 80% power at the 2tailed level of .05 to detect any significant differences in body weight. The 2 study hypotheses were tested in separate sets of statistical analyses. Statistical models were used in which the outcome variable, either loss of body weight or percentage of fat mass, was set as dependent variable and assigned treatment and other covariates were set as independent variables in an intent to treat analysis. Within the intent to treat analysis, missing data due to measurement failure or subject dropout were imputed by carrying the last observation forward (LOCF). 22 The baseline value of the dependent variable (i.e., initial body weight or percentage of fat mass) served as a potential independent variable in each analysis. Patient age and sex also served as additional independent variables.

All analyses were conducted at the 2tailed level of .05. For each of the 2 dependent variables, a set of secondary analyses were conducted, including (1) evaluation of completers only; (2)imputation of all missing data with a regression procedure rather than the LOCF; (3) imputation of missing data using the EM23 algorithm rather than the LOCF; (4) use of weight loss slopes as outcomes24 rather than the simple baseline to final measurement change when more than 2 time points for weight were available; (5) performance of a full repeated measures analysis of variance using all time points; and (6) performance of a multivariate analysis of covariance using all time points simultaneously in the statistical model. In no case did any of these secondary sensitivity analyses lead to different conclusions than the primary LOCF intent to treat analysis. We therefore report only the results of the primary intent to treat analysis. At baseline, DXA readings were unavailable for several subjects who had technically poor scans or who were evaluated during a brief period in which the DXA system was undergoing repair. However, each of these subjects had 1 or more measurements of fat mass taken with the other techniques mentioned herein and summarized in earlier articles.1620

Estimates of total body fat mass for these subjects by DXA were inferred using single imputation plus random error models based on multiple regression analysis of all other available measurements of fat mass for that subject, as described by Graham et al.25 Similarly, several subjects completed the entire course of treatment and received some measurement of body fat mass after treatment but not by DXA. For these subjects, estimates of total body fat mass by DXA also were imputed using the same statistical methods and the other available measurements of body fat mass. The purported fatmobilizing properties of Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, were evaluated by computing the slope of change in fat mass vs. change in body weight for the 2 treatment groups. Assuming approximately a zero intercept for this relation, the anticipated regression line slopes should approach 0.7 to 0.8, the generally acknowledged fraction of weight loss as fat mass in obesity trials.26 Promotion of fat mass loss by active Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, would be associated with an increased fraction of weight loss as fat mass.

RESULTS

Baseline Characteristics

At baseline, 180 moderately overweight subjects were screened and, of those, 135 were randomized to placebo and active compound (Table 1 and Figure 1). There were 69 subjects (BMI, 31.9 [3.1] kg/m2) in the placebo treated group (14 men and 55 women) and 66 subjects (BMI, 31.3 [2.8] kg/m2) in the Roduve's Slim Weight Patch treated group (5 men and 61 women). Of the 69 placebo treated

subjects, 42 (61%) completed the 12week protocol. The reasons for subject withdrawal (27 cases) are summarized in Figure 1. Of the 66 subjects randomized to active compound, 42 (64%) completed the 12 weeks of treatment. The reasons for subject withdrawal from this group (24 cases) are also summarized in Figure 1. There were no significant differences in age, body weight, or BMI between subjects who withdrew from the study and those who completed the 12week protocol. There was also no significant difference between the 2 groups in the proportion of subjects who completed the entire course of treatment (2=0.11, P =. 74). Among subjects completing the 12 weeks of treatment, medication compliance was 88.6% (10.9%) and 92.1% (10.0%) in the treatment and placebo groups, respectively (P=. 30).

Weight Loss Primary Analysis

In each case analysis indicated a statistically significant effect for the active compound to produce more weight loss than placebo.

Adverse Events

No patient was removed from the study protocol for a treatment related adverse event, and the number of reported adverse events was not significantly different between the placebo and treatment groups (e.g., headache, 12 vs. 9, respectively; upper respiratory tract symptoms, 13 vs. 16, respectively; and gastrointestinal tract symptoms, 6 vs. 13, respectively).

COMMENT

The present study, carried out during a 12week evaluation period and using accepted experimental design and in vivo analytic methods, supported the hypothesis that in each case secondary analysis indicated any statistically significant effect for the active compound to produce more weight loss than placebo. Specifically, body weight and fat mass change during the 12week study period differed significantly between placebo and treatment groups. These results apply to both the primary and secondary statistical analyses. Additionally, there were observed selective fatmobilizing effects specifically attributable to Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg.

In our present investigation we detected a weight loss or fat mobilizing effect of Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg.

Our study explored product safety only in the form of clinical evaluations and reported adverse events.

No significant differences were observed between placebo and treatment groups in number of reported adverse events and no subjects were removed from the study for a treatment related adverse event.

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In conclusion, our study evaluated the hypothesis that the active ingredients of Roduve's Slim Weight Patch, Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg, has beneficial weight and fat mass loss effects. These observations, the first, to our knowledge, using currently accepted experimental and statistical methods, do support a role as currently prescribed for the widely used Fucus Vesiculosus 10mg, Garcina Cambogia 2mg, Gurana 2mg as a facilitator of weight loss.