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RE: Forskolin and Its Potential in Controlling Obesity

Lieberman S. A new potential weapon for fighting obesity: forskolin—the active diterpene in Coleus. *Altern Complement Ther.* December 2004:330–333.

Obesity in the United States has increased at "an epidemic rate" over the last 20 years.¹ The percentage of U.S. adults classified as overweight increased from 56% in 1994 to 65% in 2002, and obesity increased from 23% to 30% during this same time period. Approximately 16% of children and adolescents 6 to 19 years old were overweight in 2002.²

Obesity is defined as an excessively high amount of body fat relative to muscle mass. There are many ways to measure obesity, including skin fold measurements, waist-to-hip circumference ratio, ultrasound, computed tomography, magnetic resonance imaging, and more. One of the most commonly used measurements, however, is the body mass index (BMI), which calculates the ratio of weight-to-height, using the equation weight in centimeters divided by height in meters squared (wt / ht^2). Overweight is defined by the World Health Organization (WHO) as a BMI of 25-29.9, while a BMI of ≥ 30 is considered obese. Obesity is further divided into grades I, II, and III. Grade I obesity is a BMI of 30-34.9, Grade II is a BMI of 35-39.4, and Grade III obesity is a BMI ≥ 40 .

The health consequences of being overweight are wide ranging. It is a major risk factor for diabetes; cardiovascular disease, including hypertension, coronary heart disease, angina pectoris, congestive heart failure, and stroke; gallstones; sleep apnea; some cancers, such as endometrial, breast, prostate and colon; complications of pregnancy; incontinence; and depression.¹ Obesity can lead to an early death and might decrease or eliminate the increased life expectancy in the U.S. attained during the last century.³

Strategies to help people lose weight are in high demand. Forskolin, an extract from coleus (*Coleus forskohlii* a.k.a. *Plectranthus barbatus*), might provide additional support for people trying to lose weight. Coleus is native to Nepal, India, and Thailand. It has traditionally been

used in Ayurvedic medicine to treat skin rashes, asthma, bronchitis, insomnia, epilepsy, and angina pectoris.

The present study reviewed the potential of ForsLean[®] (Sabina Corporation, Piscataway, New Jersey), an extract of coleus standardized to 10% forskolin to decrease fat mass and increase lean body mass in overweight and obese volunteers. Four clinical trials have been conducted. One study provided 125 mg ForsLean (12.5 mg forskolin) twice daily, while 3 other trials administered 250 mg ForsLean (25 mg forskolin) twice daily. Three of the 4 trials resulted in significant decreases in fat mass, while 2 of the 3 high-dose trials showed significant decreases in fat mass and significant increases in lean body mass.

The low-dose trial, providing 125 mg ForsLean 2 times a day, was a 12-week, open field trial on 14 overweight and obese volunteers (13 women and 1 man), with an average BMI of 29.9 ± 4.31 .⁴ Average body weight significantly decreased from 74.1 ± 11.98 kg (163.36 ± 26.41 lbs) at baseline to 73.5 kg (162.04 lbs) after 12 weeks ($P < 0.05$). Similarly, average BMI decreased to 29.49 ($P < 0.05$). Average body fat percentage decreased from 38.2 ± 4.87 at baseline to 37.1 after 12 weeks ($P < 0.01$). Lean body mass and systolic and diastolic blood pressure were not changed compared to baseline.

The first high-dose trial was a small study of 6 overweight women who took 250 mg ForsLean (25 mg forskolin) 30 minutes before a meal twice daily for 8 weeks.⁵ The study was not blinded or placebo controlled, and volunteers were instructed not to change their exercise or dietary habits. Compared to baseline percent body fat significantly decreased from 33.63 ± 3.02 at baseline to 30.10 ± 4.34 at 4 weeks, and 25.88 ± 4.77 at 8 weeks ($P < 0.05$). Percent lean body mass significantly increased from 67.07 ± 3.02 at baseline to 69.90 ± 4.34 and 74.13 ± 4.77 at 4 and 8 weeks, respectively ($P < 0.05$). Volunteers also experienced significant weight loss during the trial ($P < 0.05$), dropping a mean of 4.3 pounds after 4 weeks and 9.17 pounds after 8 weeks. Systolic and diastolic blood pressure decreased (values not reported).

The second high-dose trial was a randomized, double-blind, placebo-control study that enrolled 60 obese volunteers, between 25 and 45 years old.⁶ All volunteers had BMIs between 28 and 40 and/or body-fat percentage above 30 in men and 40 in women. Volunteers were randomized to receive 250 mg ForsLean or placebo twice daily. Treatment with ForsLean resulted in a significant decrease in average body weight compared to placebo (-3.81 pounds vs. $+0.5$ lbs, respectively; $P = 0.05$). Similarly average percent body fat significantly decreased in the treatment group compared to control (-0.46% vs. $+0.68\%$, respectively; $P = 0.05$). Significant increases in lean body mass were experienced in volunteers taking ForsLean compared to control ($P = 0.05$). High-density lipoprotein (HDL) significantly increased while the ratio of total cholesterol-to-HDL significantly decreased in the treatment group (P -values not reported). HDL and a lower total cholesterol-to-HDL ratio are considered protective against cardiovascular disease.

The only negative trial involved 19 sedentary, overweight women who supplemented with 250 mg ForsLean twice daily for 12 weeks.⁷ No significant changes in fat mass, fat-free mass, or body fat was detected. However, volunteers did report significant decreases in

hunger ($P = 0.02$) and increased feeling of fullness ($P = 0.04$). Although not discussed by the author, when the negative results of this trial are viewed with respect to the positive studies, the effect of coleus on weight loss are probably most pronounced in people who are at least somewhat active.

Toxicology studies showed an LD_{50} , the lowest dose at which 50% of experimental animals die, to be 3100 mg/kg. An Ames test for mutagenicity, a standard test to determine the potential carcinogenicity of a substance, concluded, "no mutagenicity was associated with ForsLean." No adverse effects on muscle and liver enzymes, electrolytes, thyroid stimulating hormone, and heart rate were reported in any of the studies.

Coleus may be a safe and effective supplement to aid in weight loss. When combined with exercise and a healthy diet, the effects are expected to be even greater than with coleus alone. High blood pressure and unhealthy lipid profiles are common in overweight and obese people, and supplementing with coleus may have the additional benefit of helping to normalize these conditions. However, when added together the results of the small studies reported above provide no convincing evidence that the Coleus extract conclusively reduces obesity.

—John Neustadt, ND

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