

Case #1416: A Case Study Evaluating the Effects of a Plant Sterol and Soy Protein Medical Food Program and an RIAA/Acacia Nutritional Supplement for Insulin Function Support in an Obese Patient with Metabolic Syndrome

Robert H. Lerman, MD, PhD
Functional Medicine Research CenterSM, Gig Harbor, WA
98332

PURPOSE

The purpose of this study was to assess the effectiveness of a plant sterol and soy protein medical food (provided in powdered beverage form) used in combination with an RIAA/Acacia nutritional supplement for insulin function support—along with lifestyle modifications and other targeted nutritional support—in an obese patient with metabolic syndrome.

PATIENT'S PRESENTATION AND HISTORY

A 61-year-old obese Caucasian female presented with concerns about her weight, beginning 10 years prior with a history of unsuccessful diets and weight fluctuations. The patient had qualified 3 months prior to this case study for a metabolic syndrome study at the FMRC (weight: 190 lb; BMI: 34 kg/m²) and was instructed to begin a dietary supplement containing a combination of reduced iso-alpha acids (RIAA) from hops (*Humulus lupulus*) and *Acacia nilotica* extract, 2 tablets twice daily, and follow a lowfat American Heart Association (AHA) diet. (During the previous study, strict compliance yielded weight loss of 17 lbs, BMI improvement to 30.5 kg/m², and improvement in metabolic syndrome lab markers.) Her current exercise regimen was 50 minutes of walking, 5 times weekly. The patient also currently suffered from hypertension, acid reflux, and depression—all controlled by medications.

The patient's medical history included migraines after menopause, hemorrhoids, and hyperlipidemia. Previous surgeries included an appendectomy in 1968. She had a family history of congestive heart failure, type 2 diabetes, hypertension, heart disease, and cancer.

Patient's Objective Information

- HT: 63"; WT: 173 lb; BP: 133/77
- BMI: 30.1 kg/m²
- Prescriptive medication: atenolol, 100 mg qd, lisinopril, 20 mg qd, and hydrochlorothiazide (HCTZ), 25 mg qd for hypertension; ranitidine, 300 mg bid for acid reflux; and fluoxetine 40 mg qd for depression
- Non-prescriptive medication/supplements: RIAA/Acacia supplement, 2 tablets bid; baby aspirin, 1 tablet qd; multivitamin/mineral, 1 tablet qd
- Significant laboratory findings: elevated total cholesterol (tChol), LDL-cholesterol (LDL-C), and tChol to HDL-cholesterol (HDL-C) ratio; elevated hs-CRP

PLAN AND RESULTS

The patient was instructed to:

- Discontinue AHA diet and start low-glycemic-load (LGL) diet with no caloric restrictions
- Continue RIAA/Acacia supplement, 2 tablets bid

4 Weeks After Starting the Program

The patient lost 10 lbs after following the LGL diet and increasing exercise to walking 3 miles 6 times weekly. She reported less cravings and not being as hungry as she was on AHA diet. The patient was then instructed to add:

- Plant sterol/soy protein medical food beverage, 2 scoops twice daily

16 Weeks After Starting the Program

The patient weighed in at 157 lbs (cumulative weight loss of 16 lb) and reported moderate compliance with the diet. She was feeling well and walking 4 miles 4 times weekly, but noted some hair loss. The patient was advised to:

- Add ground flaxseed, 1 Tbsp. bid
- Begin zinc arginate/glycinate combination supplement, 20 mg daily

22 Weeks After Starting the Program

The patient was pleased with her progress and lost an additional 2 lbs. She reported feeling well, but noted that her BP was dropping to 80/50 in the evenings and causing tiredness. She reported increased family stress and no decrease in hair loss. The patient was advised to continue the prescribed diet and supplementation and to:

- Add micro-filtered whey protein supplement, 1 scoop bid (16 g protein/svg)

27 & 31 Weeks After Starting the Program

At 27 weeks, the patient's weight was at 150 lbs (a 40 lb decrease in 10 months) and her BP had stabilized. She reported feeling "wonderful, great" with abundant energy and continued to walk 10,000 to 12,000 steps daily. She reported liking both the diet and medical food shakes, and had incorporated meditation several times daily to help her relax. Her hair loss had decreased. At 31 weeks, the patient had only a slight weight gain to 152.6 lb, and reported a cessation of hair loss. The patient was instructed to continue on the plan and discuss possible discontinuation of HCTZ with her primary physician.

21% Decrease in LDL-Cholesterol

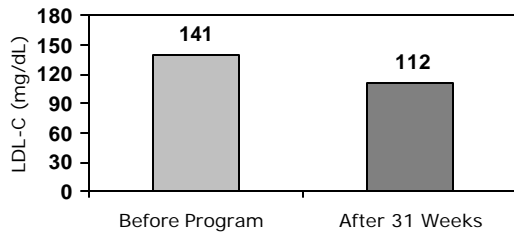


Figure 1. After 31 weeks, the patient's fasting LDL-C level decreased from 141 mg/dL to 112 mg/dL (ref. range: 95-130 mg/dL), suggesting notable improvement.

10% Improvement in BMI

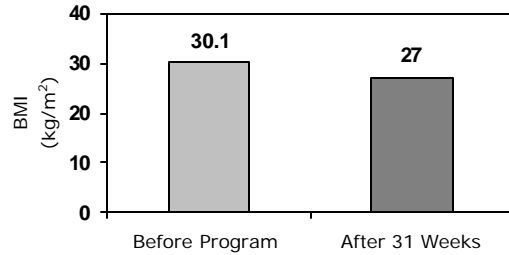


Figure 4. After 31 weeks, the patient's BMI improved from 30.1 kg/m² to 27 kg/m², re-classifying the patient as overweight rather than obese (overweight ref. range: 25-29.9 kg/m²). An improvement in BMI is associated with a significant reduction in disease risk.

24% Increase in HDL-Cholesterol

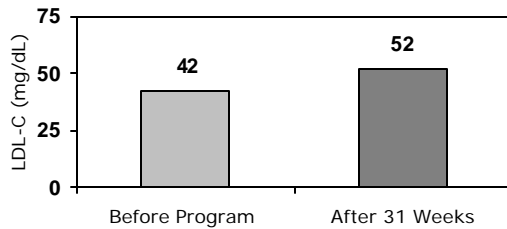


Figure 2. The patient's fasting HDL-C level ("good" cholesterol) increased from 42 mg/dL to 52 mg/dL (ref. range: 45-60 mg/dL), suggesting an improvement after 31 weeks.

69% Decrease in hs-CRP

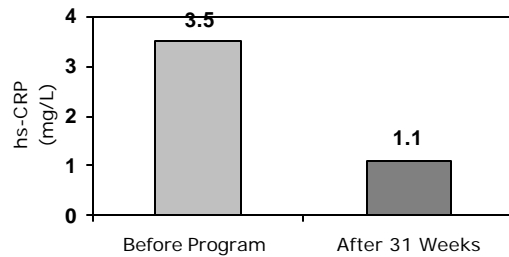


Figure 5. The patient's hs-CRP level was reduced after 31 weeks from a moderate risk range at 3.5 mg/L to a low risk range at 1.1 mg/L (low risk ref. range 0.7-1.1 mg/L). This result suggests a significant reduction in an important marker of cardiovascular disease.

27% Decrease in tChol/HDL-C Ratio

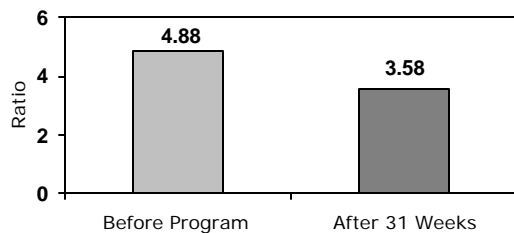


Figure 3. The patient's fasting tChol/HDL-C ratio decreased from 4.88 to 3.58 (ref. range: = 4.5) after 31 weeks. The result suggests an improvement in lipid levels.

SUMMARY

This case study suggests that a targeted nutritional support program that incorporates a plant sterol and soy protein medical food, dietary supplement for insulin function support, and lifestyle modifications and other targeted nutritional support can improve blood lipid levels and other aspects of health associated with metabolic syndrome.

NOTE

The information provided in this case study describes the results of one patient under the care of a licensed healthcare practitioner and may not be a typical response. The plant sterol and soy protein medical food discussed in this study is to be used under the supervision of a physician or other licensed healthcare practitioner.

Financial support for this study was provided by Metagenics, Inc. This study was conducted at the Functional Medicine Research CenterSM (FMRC), the clinical research arm of Metagenics, Inc. Robert H. Lerman, MD, PhD, is the Medical Director at the FMRC.

[†]Body Mass Index (BMI) is computed by the weight (kg) divided by the square of the height (m).

©2004 Functional Medicine Research Center

Case Study: A Case Study Evaluating the Effects of a Plant Sterol and Soy Protein Medical Food Program and an RIAA/Acacia Dietary Supplement for Insulin Function Support in an Obese Patient with Metabolic Syndrome. Metagenics, Inc; CS00324. MET1416 11/06