Changes in weight loss and lipid profiles after a dietary purification program: a prospective case series

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Erica Callahan*  
Assistant Professor, Clinic, New York Chiropractic College, Seneca Falls, NY  
Erica Callahan: ude.ccyn@nahallace  
*Corresponding author. New York Chiropractic College, 2360 State Route 89, Seneca Falls, NY 13148. Tel.: + 1 315 568 3293; fax: + 1 315 568 3204. Email: ude.ccyn@nahallace

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Abstract

Objective

The purpose of this case series was to describe immediate changes to weight and lipid profiles after a 21-day Standard Process whole food supplement and dietary modification program.

Methods

Changes in weight and lipid profiles were measured for 7 participants (6 men and 1 woman) participating in a 21-day program. The dietary modifications throughout the Standard Process program were consumption of (1) unlimited fresh or frozen vegetables and fruits and preferably twice as many vegetables as fruits, (2) ½ to 1 cup of cooked lentils or brown rice each day, (3) 4 to 7 teaspoons of cold pressed oils per day, and (4) at least 64 oz of water a day. After day 10 of the program, participants were allowed to consume 1 to 2 servings of baked, broiled, or braised poultry or fish per day. Participants consumed a whey protein-based shake as meal replacement 2 times per day. Nutritional supplementation included a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and “green food” supplementation on days 8 to 21.

Results

Weight loss ranged between 5.2 (2.4 kg) and 19.9 lb (9.0 kg) (average, 11.7 lb; 5.3 kg). Total cholesterol levels decreased with ranges between 11 and 77 mg/dL, and low-density lipoprotein cholesterol levels decreased in a range between 7 and 67 mg/dL.

Conclusion

After participating in a dietary program, the 7 participants demonstrated short-term weight loss and improvements in their lipid profiles.
Key indexing terms: Weight reduction programs, Overweight, Obesity

Introduction

National statistics indicate that 33% to 36% of the US population is obese.\textsuperscript{1} Diets emphasizing caloric restriction, without malnutrition of essential nutrients and regardless of dietary macronutrients, are promoting healthy weight loss, improving lipid profiles and fasting insulin levels, inducing metabolic adaptations, and reducing oxidative stress.\textsuperscript{2-6} In addition, commercially available meal replacement products, such as Medifast (Medifast Inc., Owings Mills, MD),\textsuperscript{7} NutriSystem (Nutrisystem, Fort Washington, PA),\textsuperscript{8} Healthy Solutions (Healthy Solutions LLC, Scottsdale, AZ),\textsuperscript{9} Ultra-Slim Fast (Unilever Slim Fast, London, UK),\textsuperscript{10} and Isagenix 28-Day Program (Isagenix International LLC, Chandler, AZ),\textsuperscript{11} are safe and effective weight loss products. With so many weight management programs available, how can a health care provider recommend the most appropriate evidence-based intervention for each of their patients?

Adherence to the diet plan is the critical factor for weight loss, weight maintenance, and health benefits. Evidence-based commercially available programs and products require minimal professional intervention and address the individualized eating habits of a diverse patient population. However, the development of nutrient profiling systems with an emphasis on whole foods philosophy and patient education may induce behavioral changes in eating habits.\textsuperscript{12}

Consequently, a better quality diet characterized by increased consumption of more fruits, vegetables, whole foods, and decreased consumption of saturated fats, sugar, sodium, and processed foods may allow individuals to maintain a healthy weight and prevent chronic diseases associated with being overweight and obese to include cardiovascular disease, type II diabetes, and certain types of cancers.\textsuperscript{13,14}

The Standard Process Purification Program (SPPP) (Standard Process Inc, Palmyra, WI) is used by some chiropractors as a nutritional intervention for their patients.\textsuperscript{15} The 21-day SPPP is a holistic therapy designed to create a synergistic effect of whole food supplementation and dietary modifications with energy restriction.\textsuperscript{15} The dietary modifications with energy restriction emphasize consuming controlled portion sizes of low–energy-density foods, for example, fruits, vegetables, and whole grain products, and have been fully described by Powell and Leonard.\textsuperscript{15} The program includes 2 meal replacement shakes and introduces moderate amounts of protein from vegetable and whey sources on days 11 through 21 while restricting or eliminating meat, refined oils, and refined carbohydrates.\textsuperscript{15} In addition to the whey protein–based shake, the nutritional supplementation program includes a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and “green food” supplementation on days 8 to 21.\textsuperscript{15} Based upon a retrospective medical record review, Powell and Leonard\textsuperscript{15} reported that SPPP improved lipid profiles and weight status of 28 chiropractic patients.

As summarized by Rolls,\textsuperscript{16,17} low–energy-density diets and portion size control are 2 critical attributes underlying nutritional interventions in both the prevention and treatment of obesity. The dietary component of the SPPP incorporates both of these attributes. The attributes of regimented nutritional supplementation program are consistent with the evidence for improvements in lipid profiles and weight loss. Dietary fiber intake of more than or 22 g/d has been associated with reduction in total cholesterol and low-density lipoprotein (LDL) cholesterol in premenopausal women.\textsuperscript{18} Phytosterols are cholesterol-like substances found in plants such as oat bran. A diet high in soluble fiber pectin and phytosterols has been found to significantly reduce total cholesterol levels\textsuperscript{19} and exert a modest triglyceride-lowering effect.\textsuperscript{20} Probiotics and prebiotics may have significant health benefits on lipid metabolism, mineral absorption, and immune function via their beneficial influences on microbial ecology of the gut.\textsuperscript{21-26} Although there are limited clinical data on the role of microflora management interventions on weight loss and improved health status,\textsuperscript{27-29} probiotic and/or prebiotic nutritional supplementation and colon-cleansing products
are being promoted as critical elements for initiating and maintaining weight loss.

The development of the SPPP incorporated theoretical concepts underlying effective nutritional interventions for improvements in lipid profiles and weight status associated with reducing chronic disease risk factors. However, at present, the only published evidence on its effectiveness is a retrospective medical record review of a nonrandom series of 28 chiropractic patients who “successfully” completed the SPPP; and their patient records included pre-post lipid profiles and weight measurements. Thus, the purpose of this case series was to describe prospectively any changes to weight and lipid profiles after a 21-day SP whole food supplement and dietary modification program.

Methods

Study population

Participants were recruited from faculty, staff, and students at a chiropractic college (20-60 years of age) who were participating in a college-sponsored “Cleanse Event.” For approximately 1 month (April 2011), general campus announcements were used to advertise a “Cleanse Event”; and individuals inquiring about the “Cleanse Event” were made aware of the concurrent research study. The “Cleanse Event” was a 21-day weight management program in which volunteer participants completed the SPPP, attended weekly “Lunch and Learn” nutritional educational seminars, and received lifestyle and nutritional advice from the supervising clinician. The participants were responsible for purchasing their SPPP kits (Standard Process Inc) at a discounted price of 40% of retail. Of the 32 participants screened for the program, 7 individuals agreed to participate in the research study. All 7 participants provided written informed consent to participate in this study. The New York Chiropractic College Institutional Review Board approved all measurement and intervention procedures for the study.

During May 2011, the supervising clinician screened 32 individuals to participate in the program. During the screening visits, participants completed a health history questionnaire and were interviewed about potential food allergies. The participants self-reported any previous participation in purification or detoxification programs and any adverse effects that they experienced. The participants self-reported any known food intolerances or allergies, digestive complaints, and thyroid complaints or previous thyroid-related conditions. They also self-reported any medications, herbal remedies, or nutritional supplements that they were currently using. In addition, screenings of blood pressure and body mass index (BMI) occurred. Measurements of sitting blood pressure were from both arms using the standard clinic procedure of mercury sphygmomanometer with the Korotkoff sound technique according to the recommendations for blood pressure measurements in humans. Body mass index was calculated from the measured body weight and height (kilograms per square meter). To participate in this prospective case series, the BMI inclusion criterion was 25 to 34.99 kg/m². The exclusion criteria for participating were as follows: (1) taking any prescription medication including birth control medications; (2) hypertension and borderline hypertension defined as systolic blood pressure of at least 135 mm Hg and/or diastolic blood pressure of at least 85 mm Hg; (3) neurological disorders including peripheral neuropathy; (4) diabetes; (5) thyroid disorders; (6) irritable bowel disease or colitis; (7) eating disorders; and (8) food sensitivities/allergies to the ingredients found within the nutritional supplements (including lactose- and gluten-intolerant individuals). According to the American Heart Association, at-home and ambulatory measurements of systolic blood pressure should be at least 135 mm Hg and/or diastolic blood pressure should be at least 85 mm Hg in assessing possible hypertension risk. This selected upper limit for screening participants may also account for any possible “white coat hypertension” phenomenon as described by the American Heart Association. If the participants did not satisfy any of these exclusion criteria for the program, then the inclusion criterion for participating in the case series analysis was a BMI from 25 to 34.99 kg/m² to meet the classifications of overweight or class I obesity.

Intervention
On the first morning of the program and on the morning following the completion of the 21-day program, pre-post measurements on the research participants occurred.

As previously described by Powell and Leonard, participants were instructed to increase vegetable and fruit consumption while restricting or eliminating meat, sugar, caffeine, nuts, alcohol, trans fats, and refined carbohydrates during the 21-day SPPP. The specific dietary modifications throughout the 21-day SPPP were consumption of (1) unlimited fresh or frozen vegetables and fruits and preferably twice as many vegetables as fruits, (2) ½ to 1 cup of cooked lentils or brown rice each day, (3) 4 to 7 teaspoons of cold pressed oils per day (eg, flaxseed oil, fish oil, coconut oil), and (4) at least 64 oz of spring water a day. After day 10 of the SPPP, participants were allowed to consume 1 to 2 servings (3 oz) of baked, broiled, or braised poultry or fish per day. Furthermore, as previously described by Powell and Leonard, the SPPP included whole food nutritional supplementation. In addition to the whey protein–based shake as meal replacement 2 times per day, the nutritional supplementation program included a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and “green food” supplementation on days 8 to 21.

As part of the program, there were weekly luncheons for the participants. At the weekly luncheons, the supervising clinician answered questions from the participants; and the participants shared recipes and provided peer encouragement to each other. Difficulties with adhering to the dietary modifications and adverse effects were discussed.

Data collection

Anthropometric measurements included body weight, height, BMI, and waist and hip circumferences. Anthropometric assessments were conducted with the participants wearing light clothing (gown and shorts) and barefoot. Weight was measured using a high-precision digital scale (DI-10, DIGI Matex, Inc, Singapore; 0.1-kg gradations; 225-kg capacity). Height was measured using a high-precision digital stadiometer (seca 242, Hamburg, Germany; 1-mm gradations; measuring range, 62-210 cm). Body mass index was calculated from the measured body weight and height (kilograms per square meter). A standard cloth tape marked with inches and centimeters was used to measure waist and hip circumferences. Each site was measured 3 times and the 3 most consistent measurements were averaged to enhance reliability. Body landmarks of the umbilicus and greater trochanters were used to standardize measurements of pre-post waist and hip circumferences, respectively, to enhance reliability and validity. The waist-to-hip ratio and waist-to-height ratio were calculated.

A fasting lipid profile was obtained from each participant, pre-postintervention. Professional services were obtained from a local hospital to perform venipuncture and analyze the venous plasma samples. Venous plasma (lithium heparin) was collected by standard venipuncture technique from the antecubital vein. Venous plasma samples were analyzed using routine clinical chemistry methods to measure total cholesterol, LDL cholesterol, high-density lipoproteins (HDL cholesterol), and triglycerides.

A visual analog scale was used to assess perceived energy level, weight management control, and gastrointestinal health. The context of administrating the 10-cm visual analog scale required that the participants rate their energy level with anchors set at “no energy at all” to “full of energy,” weight management control with anchors set at “always worrying about my weight” to “no problems with weight control,” and gastrointestinal health with anchors set at “daily gastrointestinal symptoms” to “no symptoms at all.” Gastrointestinal symptoms included bloating, belching, flatulence, diarrhea or constipation, heartburn, and nausea.

Participants kept a daily diary of any adverse effects that they experienced. The participants were instructed to write “none” or “no adverse effects” if they did not experience any adverse effects on a given day. The diaries were collected weekly, and the participants had the contact information of the principal investigator to ensure adequate safety monitoring during the 21-day intervention. The participants also completed a daily checklist regarding their supplementation schedule adherence.
The diary allowed us to monitor any adverse effects, and the completed checklist allowed us to monitor participant compliance to the recommended supplementation schedule. The participants were not asked to record dietary food intake during the 21 days. Compliance to the dietary recommendations was gauged using verbal reports by each participant during the weekly luncheons as part of the program.

Data analyses

The primary outcome measures were weight and lipid profiles pre- and postintervention. Secondary outcomes were BMI; waist and hip circumferences; waist-to-hip and waist-to-height ratios; and perceived changes in energy level, weight management control, and gastrointestinal health. Pre-post data from each of the cases in the series were presented in . Interpretations of the data findings were based upon meaningful clinical differences for each of the outcome measures.

Anthropometric measurements

Fasting lipid profiles (milligrams per deciliter)

Visual analog scale data (0-10 cm): ratings of energy level, weight management control, and gastrointestinal health

Results

Study population

Of the 32 individuals screened and enrolled in the program, 6 men and 1 woman (n = 7; 26 ± 2.1 years) qualified for the analysis according to the inclusion and exclusion criteria. Twenty-three individuals did not meet the BMI inclusion criterion of 25 to 34.99 kg/m$^2$. Two individuals were currently taking prescription medications. The 7 participants enrolled in the case series analysis reported that they engaged in an exercise routine (either aerobic exercise or resistance training) at least 3 times per week, and they were instructed to maintain their levels of physical activities and exercise during the SPPP.

Compliance

During the weekly luncheons during the program, the 7 participants reported that they followed the dietary recommendations. Overall, the 7 participants were compliant with consuming 2 whey protein–based shakes as meal replacements and following the nutritional supplementation program. On days 12 and 21, 1 participant reported not consuming SP Complete shakes as meal replacements. On day 5, 1 participant reported having 1 less SP Cleanse serving than recommended (14 SP Cleanse pills instead of 21 SP Cleanse pills per day). On days 18 and 20, 1 participant reported having 1 less SP Green Food serving than recommended (5 SP Green Food pills instead of 10 SP Green Food pills). On days 6 and 16, 1 participant reported consuming only 1 SP Complete shake. In summary, there were 7 reported days in which 1 participant did not fully comply with treatment recommendations. The estimated compliance with the allocated treatment was 95% (7 participants × 21 days = 147 compliance days; minus the 7 reported noncompliance days; 140/147 = 95%).

Outcome measures

summarizes the anthropometric measurements. Weight loss was between 5.2 lb (2.4 kg) and 19.9 lb (9.0 kg) with an average weight loss of 11.7 lb (5.3 kg). Decreases in BMI were between 1.3 and 4.2 kg/m$^2$ with an average decrease of 2.3 kg/m$^2$ pre-post intervention. Pre-post intervention, the average decrease in waist circumferences was 1.3 in with a concomitant decrease of 0.01 in the waist/height ratio. Participant 4, with the least amount of weight loss, did not experience decreases in waist circumference or waist/height ratio. With the exception of participant 4, hip circumferences decreased between 0.5 and 3.0 in. There were no systematic changes among the
participants for the waist-hip ratio pre-post intervention.

summarizes the lipid profiles. Pre-post intervention, decreases in total cholesterol levels and LDL cholesterol levels were between 11 and 77 mg/dL and between 7 and 67 mg/dL, respectively. Total cholesterol levels decreased on average from 178 mg/dL preintervention to 134 mg/dL postintervention with a concomitant decrease in LDL levels from 104 mg/dL preintervention to 80 mg/dL postintervention. With the exception of participant 1, HDL levels decreased between 3 and 22 mg/dL with an average decrease of 7 mg/dL. The LDL to HDL ratios decreased on average 0.27 point. There were no systematic changes among participants for triglyceride levels pre-post intervention.

In general, participants reported improvements in energy levels, weight management control, and gastrointestinal health postintervention.

Adverse effects

There were a total of 169 recordings in the adverse effects logs (7 participants recording symptoms for 21 days each, with some participants reporting more than 1 symptom per day). The percentages of adverse effects were calculated for 5 different categories: (1) no adverse effects at a frequency of 58%, (2) headaches at a frequency of 13.6%, (3) gastrointestinal symptoms at a frequency of 14.2%, (4) fatigue and muscle soreness at a frequency of 8.3%, and (5) hunger and food cravings at a frequency of 5.9%. With the exception of gastrointestinal symptoms reported by only 1 participant throughout week 3, all other adverse effects subsided after week 2.

Discussion

The findings of this case series showed similar results to the retrospective medical record review by Powell and Leonard that the SPPP is a nutritional intervention that may assist with short-term weight loss and lipid profile improvement. Clinically meaningful decreases occurred for weight loss (11.2 vs 9.0 lb; 5.1 vs. 4.1 kg), total cholesterol levels (44 vs 47 mg/dL), and LDL cholesterol levels (24 vs 35 mg/dL) in both the current study and the retrospective medical record review by Powell and Leonard, respectively. The dietary component of the SPPP is consistent with the findings that low–energy-density diets and portion size control are 2 critical attributes underlying weight loss. The whole food properties of the regimented nutritional supplementation program to include whey-based protein meal replacement shakes, fiber, phytosterols, prebiotics and probiotics, and 1 to 2 servings of lean meat (days 11-21) are consistent with the evidence for improvements in lipid profiles and weight loss (“Introduction” and below). The weekly luncheons by providing patient education on the benefits of low–energy-density diets, that is, whole foods philosophy of healthy eating, mostly likely contributed to our findings on the SPPP.

For overweight and obese adults, that is, BMI from 25 to 34.99 kg/m², a rapid weight loss of 3.3 to 5.5 lb/wk (1.5 to 2.5 kg/wk) or approximately 2% to 3% of initial body weight per week is deemed safe under the supervision of a health care provider. Weight loss for all individuals in the case series met this safety criterion for rapid weight loss. There were improvements in the secondary anthropometric outcome measures, but the pre-post changes were not clinically meaningful differences with the exception of BMI. On average, BMI shifted from obese category to the overweight category, with 5 of the 7 participants changing from being classified as obese to overweight or overweight to normal weight. Waist-to-height ratios less than 0.50 and waist-to-hip ratios less than 0.83 for women and less than 0.90 for men are associated with a decreased risk for cardiovascular disease. Reducing the risk of cardiovascular disease as defined by these anthropometric indices was not observed.

Although total cholesterol levels were less than 200 mg/dL at preintervention (178 mg/dL), the pre-post intervention decrease of 44 mg/dL was still deemed clinically meaningful, as a total cholesterol level of 131 mg/dL after the SPPP reflects a more favorable lipid profile. In the current study and previously, participants with total cholesterol levels greater than 200 mg/dL experienced clinically meaningful decreases. For LDL cholesterol levels, a target of
100 mg/dL is ideal for reducing the risk of cardiovascular disease, with the most recent recommendation to change the ideal target to less than 70 mg/dL. The SPPP reduced LDL cholesterol levels from an average of 104 to 80 mg/dL (inducing decreases in all 7 participants). However, 2 participants still demonstrated post-SPPP total LDL cholesterol levels greater than 100 mg/dL, which do not achieve the ideal target of decreased cardiovascular disease risk. This was also previously demonstrated by the Powell and Leonard study in which all patients showed a reduction in LDL cholesterol levels, but the average total LDL cholesterol was 110 mg/dL.

The impact of the program on optimal levels of triglycerides, less than 150 mg/dL, was inconclusive in the current study, with Powell and Leonard reporting a decrease from 116 to 89 mg/dL. Neither the current study nor the previous study detected increases in HDL cholesterol levels to greater than 60 mg/dL. A decrease in HDL cholesterol is expected when participants are participating in a calorie-restricted, low–energy(calorie)-density dietary intervention. In addition, weight loss achieved through exercise is more effective at raising HDL cholesterol levels than dieting. Similarly, exercise, independent of weight loss and dietary changes, is an effective intervention for decreasing triglycerides. However, there is evidence that high-protein and moderate-protein weight loss diets are effective at decreasing triglycerides and increasing HDL cholesterol levels. Although HDL cholesterol levels decreased in patients, the pre and post LDL/HDL cholesterol ratio levels also decreased from an average of 2.95 preintervention to 2.68 postintervention. According to recommendations by the National Cholesterol Education Program Adult Treatment Panel III, an LDL/HDL cholesterol ratio of around 2.5 is optimal for decreased cardiovascular disease risk.

Low-calorie, protein-rich weight loss diets reduce fat mass while maintaining lean body mass and enhancing satiety. Short-term, high-protein diets reduced total cholesterol levels and LDL cholesterol levels in overweight and obese individuals. The inclusion of whey protein sources into a low-calorie dietary intervention may be more effective than soy protein toward enhancing weight loss, reducing total cholesterol levels, and maintaining lean body mass. In addition, increases in protein intake during weight maintenance stimulate fat oxidation, which results in decreases in fat mass. Perceptions of improvements in energy levels, weight management control, and gastrointestinal health were also consistent with low-calorie, protein-rich weight loss diets.

Limitations and future studies

Although the case series analysis was prospective, participant selection bias limits the generalizability of the results. Sample size and sex bias (6 men and 1 woman) limit the generalizability of the results. This was a short-term study; thus, long-term effects of the dietary modifications and whole food supplementation with respect to adherence, weight control, and health benefits are unknown. The SPPP is designed to work synergistically using both dietary modifications and whole food supplementation. However, the multicomponent nature of the program and the inclusion of weekly patient education preclude any conclusions on the independent effects of dietary modifications and whole food supplementation on weight loss and improvements in lipid profiles.

Future studies should be performed including randomized controlled trials to compare the SPPP with other dietary supplements and programs. When planning these trials, their validity depends upon adequately defining (1) hypotheses; (2) recruitment strategies; (3) sampling of patient populations to include eligibility criteria, sample size, and randomization procedures; (4) therapeutic and control interventions with procedures to monitor treatment adherence and adverse events; (5) blinding; (6) primary and secondary outcome measures; and (7) appropriate statistical procedures. The randomized trial needs to address the sustainability of dietary modifications after the 21-day “detoxification” phase and the long-term benefits on weight management and chronic disease risk factors. Given the current obesity epidemic and diversity of patient populations and their eating behaviors, there is a critical need for a vast array of evidence-based weight management programs that health care
professionals can offer to their patients to promote long-term weight control and health.\textsuperscript{3,60-62}

**Conclusions**

After participating in the short-term SPPP, which included dietary modification and whole food supplementation, the 7 participants experienced weight loss and improvements in their lipid profiles. Participants in this study showed overall compliance and reported only a few mild adverse effects. The findings have practical implications from the perspective of offering nutritional interventions within a primary care setting such as a chiropractic office.

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No funding sources or conflicts of interest were reported for this study.

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