

Replacement Meal: Effectiveness of a Soluble Powder Rich in Fibers and at Low Glycemic Index in Overweight but Not in Obese Patients

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Abstract

Active lifestyle and qualitative and quantitative diets are the best way to lose weight. In our study we have assessed the effectiveness and tolerability of a soluble powder rich in fibers and at low glycemic index and used, with a portion of fresh fruit, as replacement meal (for a total calorie intake ranging from a minimum of about 130 kcal to a maximum of 260 kcal) in 52 overweight/obese subjects of the outpatient clinic of the Italian National Research Council (CNR) of Rome already in treatment with a low-fat low-carbohydrates qualitative diet. The study was a parallel, prospective trial of two randomized sample groups, "intervention" (26 subjects) and "control" (26 subjects). After 8 weeks, the treatment based on the replacement meal has improved the results obtained through the qualitative diet alone above all in the overweight subjects: 11/16, versus only 2/16 in the control group, became ranged within normal weight. On the contrary, the majority of obese subjects didn't change their BMI classification suggesting that, in case of obesity, a controlled quantitative correction with weighing food portions could be a better strategy than low-calorie replacement meal.

Keywords

Overweight, Obesity, Cardiovascular Risk, Functional Foods, Replacement Meal

1. Introduction

In Italy, just like in other industrialized countries, cardiovascular diseases (CVD)

are the leading cause of death among the general population, and are an increasingly onerous economic burden on the National Health Service [1]. The identification of factors that influence cardiovascular risk, which contributes to varying degrees to determining the scale of CV, is therefore an important task of both General Practitioners and cardiovascular specialists. Numerous observational studies have shown that being overweight and in particular, obese, is a major risk factor not only for CVD, but also for cancers [2]. The best way to lose weight is to follow a diet and lead an active lifestyle. The dietary-nutritional approach must be based on both qualitative correction (reducing fat and carbohydrate intake, especially simple carbohydrates), and quantitative correction (weighing food portions, or eating low-calorie “replacement” meals) [3].

2. Aim of the Study

Assess the effectiveness and tolerability of IUSVIA, a soluble powder rich in fibers and at low glycemic index (GI) used as replacement meal in overweight/obese subjects of the outpatient clinic of the Italian National Research Council (CNR) of Rome.

3. Patients and Methods

The study, conducted from February to May 2016, is part of the programs for health promotion in the workplace by the Health and Safety Office of CNR of Rome (PROmozione e tutela della SALute, so called “Pro.Sa. Project”) in the field of cardiovascular health [4]. This project, active from 2000, has been tailored for the staff members of the headquarters of the CNR in Rome. The prevention program consists in screening of major cardiovascular (CV) risk factors, calculation of individual CV risk profile over the next 10 years using a computerized programme based on data from the Framingham Heart Study [5], identification of subjects at risk and inclusion in a programme of a healthier life style (and, where required, pharmacological treatment). The low-calories, low glycemic index, soluble plant powder used as replacement meal consisted of one dose (two 13 g scoops for a total of 26 g, providing 88 kcal) of buckwheat flour, lupin flour, rice fibre, hazelnut flour, carob flour, manna, oat fibre, button mushrooms (*Agaricus bisporus*), and vitamin D2 (Ergocalciferol) (Table 1), mixed into a “smoothie”, in a glass of water or low-fat milk (about 60 kcal) or fruit juice (about 60 - 70 kcal) or vegetarian juice with almonds (about 40 kcal) or soy (about 60 kcal) or barley (about 70 kcal) or small pot of low-fat yogurt (about 60 kcal), according to personal preference, accompanied by one serving of fruit (from 40 to 100 kcal), for a total calorie intake ranging from a minimum of about 130 kcal to a maximum of 260 kcal.

Fifty-two staff members of CNR patients aged >25 and <67 years old, of both genders, in primary CV prevention, that although following a qualitative low-fat, low-carbohydrates diet (Table 2), had a body mass index (BMI) ≥ 25.0 were enrolled in a parallel, prospective trial of two randomized sample groups “intervention” and “control”: 16 overweight patients (BMI ≥ 25 to 29.9) and 10 mild

Table 1. Nutritional information of IUSVIA, a soluble replacement meal powder rich in fibers and at low glycemic index.

	per 100 g	per 26 g
Energy (kcal)	344	88
Fats (g)	9.6	2.5
of which saturated fatty acids (g)	1.0	0.26
Carbohydrates (g)	40.7	10.6
of which sugars (g)	5.9	1.5
Fibre (g)	25.5	6.6
Protein (g)	11.0	2.9
Salt (mg)	500	130
Pantothenic acid (mg)	44.3	11.2
Vitamin D (mcg)	19.2	5.0
Iron (mg)	8.4	2.3
Manganese (g)	4.7	1.2

Table 2. Overweight/obesity: list of recommended foods for a qualitative low-fat, low-carbohydrates diet.

- bread, bran, rye bread, pita bread, crisp bread (without fats), high fibre breakfast cereals, muesli, popcorn (without butter)*
- plain pasta (e.g., spaghetti, fusilli, rigatoni, penne), rice, polenta, couscous*
- pizza with anchovies, mushrooms*
- consommé, vegetable soups, minestrone
- potatoes*
- low-fat meat (fat and/or skin removed): veal, lamb, pork, goat, horse, chicken, turkey, rabbit, venison, pheasant, partridge, guinea-fowl, snail, pigeon, quail, frog, ostrich (2 - 3 *times per week*)
- ham, speck (fat removed) (2 - 3 *times per week*)
- fish: anchovies, bass, bogue (sea bream), cat fish, cod, coregone, dentex, dog fish, dory, grey mullet, hake, halibut, herring, horse mackerel, lattarini, lombus, mackerel, meager (croaker), mullet, pike, red bream, saddled bream, salema (strepie), salmon, sardines, scorpion fish, skate, sole, striped bream, sturgeon, tinca, trout, two-banded bream, vendace**
- shellfish: crab, lobster, shrimp**
- molluscs: cuttlefish, hen clams, mussels, octopus, oyster, squid**
- eggs (2 - 3 *per week, preferably boiled or poached*)
- low-fat milk, soy milk, low-fat yoghurt (*daily*)
- low-fat cheeses (e.g., cottage cheese, quark, cow-ricotta) (1 - 2 *times per week*)
- legumes: beans, broad beans, chickpeas, green beans, lentils, peas (*daily*)
- all soy products (*daily*)
- all vegetables cooked, in a salad or as crudités (*daily*)
- all fresh fruits (*daily*)
- nuts: almonds, hazelnuts, peanuts, pistachio, walnuts***
- jam, marmalade***
- sorbet, jelly, meringue, puddings based on skimmed milk****
- vegetable oils (mainly olive oil, canola oil and peanut oil)***
- very low-fat (20%) margarine***
- water, unsweetened fruit juices, low-calorie drinks
- coffee, tea (*no more than 3 cups/day; to sugar use acesulfame K, aspartame, cyclamate or saccharine*)
- wine, beer (*preferably with meals and no more than 1 - 2 glasses/day*)

*Starchy can be consumed daily, but due to their high-carbohydrate content, amount of intake should be limited. Moreover, in the same meal, one carbohydrate dish excludes the other, therefore, do not combine, for example, bread and pasta, bread and potatoes, pasta and potatoes. **Marine products should be consumed at least 2 - 3 times per week. ***Due to the high energy content, the amount and frequency should be very limited. ****Due to the high energy content, avoid to the extent possible.

obese patients (BMI ≥ 30 to <35), 11 men and 15 women, mean age of 53.9 years, were enrolled in the “intervention group” (dietary treatment plus 2 scoops of soluble plant powder as a replacement meal at lunch or dinner time) versus 16 overweight and 10 mild obese individuals (10 men and 16 women), with a mean age of 52.5 years, who continued the dietary treatment only, “control group”.

To achieve a lower fat content, grilling, steaming, boiling and microwaving or barbecuing are preferable methods of cooking. The use of herbs (e.g., basil, mint, parsley, rosemary, sage), garlic, pepper, spices, tomato sauce, mustard, lemon and vinegar is suggested.

It is important to check food labels of packaged foods for fats, sugars and calories content.

Addition of salt to food while cooking or when it is served at the table, should be limited.

This recommended diet should be accompanied by a programme of regular physical activity: preferably aerobic, of moderate intensity, at least 30 minutes per day (which could also be separated into fractions), for at least 5 days per week.

Exclusion criteria included: history of CVD, heart failure, liver failure, kidney or lung disease, presence of cancer, known allergy or intolerance to components of the powder. The study complied with the ethical guidelines of the Declaration of Helsinki, the protocol was approved by the CNR of Rome and the informed consent was obtained from all patients before the inclusion in the study.

Visits were carried out at weeks 0 (baseline), 4 and 8 to assess patient compliance, to measure body weight and height in order to calculate BMI, and to measure waist abdominal circumference and blood pressure. Blood samples, obtained after 12-hours of overnight fast, were taken at weeks 0 and 8 to measure efficacy (blood sugar levels, insulin, total cholesterol, LDL and HDL cholesterol, triglycerides, uric acid), and safety/tolerability (transaminase and creatinine levels). These blood tests were carried out at the Central Laboratory of the Umberto I University Hospital, “La Sapienza” University of Rome, a center subject to internal and inter-laboratory quality controls. The computerized calculation of absolute individual CV risk of a coronary event at years 10 was performed at weeks 0 and 8. This risk was assessed according to the risk prevention estimates derived from the data of the Framingham Heart Study, starting with the age and gender of the patient and combining this data with the systolic and diastolic blood pressure values, total cholesterol and HDL-cholesterol levels, and the presence of diabetes and smoking [5]. The mean averages and standard deviations (SD) were used to describe the distribution of the continuous variables. The statistical significance of the differences in the parameters measured in both groups was assessed using Student’s T test and, for parameters with multiple measurements, with the Analysis of Variance (ANOVA). Statistical significance was set at $p < 0.05$.

4. Results

All the patients completed the study. Statistical analysis of the average baseline

values of the two groups did not show statistically significant differences. Statistical analysis of the patients in the intervention group, as regards variations in the parameters between week 0 and week 8, found a statistically significant decrease in BMI (−12.2%), abdominal circumference (−8.2%), total and LDL-cholesterol (−8.2% and, respectively, −9.7%), blood sugar (−4.9%), insulin (−18.5%) and CV risk (−20.1%) (**Table 3**). On the contrary, in the patients of the control group, statistical analysis did not show any statistically significant change between week 0 and week 8. However, the good results of the intervention group have been obtained above all in the overweight subjects: in the intervention group, 11/16 (69%) of the overweight subjects passed from overweight to normal weight (versus only 2/16, 13%, in the control group) (**Table 4**); on the contrary, in the intervention group, only 3/10 passed from obese to overweight and nobody in the control group (**Table 5**). The soluble plant powder was widely accepted in terms of palatability (with a clear preference for mixing it with milk or yoghurt) and well tolerated. Compliance was >95% and there was no change in transaminase and creatinine levels.

Table 3. Effects of IUSVIA, a soluble replacement meal powder rich in fibers and at low glycemic index, on cardio-metabolic parameters and coronary risk at 10 years in the intervention group versus control group.

	Intervention Group					Control Group				
	Baseline		Week 8			Baseline		Week 8		
	Mean	SD	Mean	SD	Δ%	Mean	SD	Mean	SD	Δ%
BMI	31.2	8.5	27.4	7.5	−12.2*	31.3	7.0	30.5	6.6	−2.6
Waist circumference (cm)	98	17.7	91	12.6	−8.2*	99	16.2	97	16.3	−2.0
Systolic blood pressure (mmHg)	134	8.8	129	7.5	−3.7	134	7.9	132	7.7	−1.5
Diastolic blood pressure (mmHg)	83	5.2	81	4.5	−1.2	84	5.4	84	5.1	0
Total cholesterol (mg/dL)	233	11.3	214	10.6	−8.2*	232	11.6	226	10.4	−2.2
LDL cholesterol (mg/dL)	154	10.6	139	9.8	−9.7*	149	8.9	147	10.2	−1.3
HDL cholesterol (mg/dL)	42	4.4	44	4.1	+4.8	44	4.7	44	4.8	0
Triglycerides (mg/dL)	184	19.7	154	16.1	−16.3	190	18.8	176	18.1	−7.4
Blood sugar (mg/dL)	107	5.9	102	6.0	−4.9*	107	6.2	106	5.7	−0.9
Insulin (mg/dL)	27	5.1	22	4.4	−18.5*	26	4.9	25	4.2	−3.8
Uric acid (mg/dL)	6.1	0.9	5.9	0.8	−3.3	6.1	0.8	6.0	0.7	−1.6
CV risk at 10 years (%)	13.9	6.2	11.1	5.1	−20.1**	12.9	6.1	12.6	6.0	−2.3

Data expressed in mg/dL, as mean average and standard deviation, Δ% versus the baseline, *p < 0.5, **p < 0.01.

Table 4. Effects of the replacement meal on BMI class: number of overweight and normal weight patients in the intervention group and in the control group at baseline and at the end of the study.

	Intervention Group		Control Group	
	Baseline	Week 8	Baseline	Week 8
Overweight	16	5	16	14
Normal weight	0	11	0	2

Table 5. Effects of the replacement meal on BMI class: number of obese and overweight patients in the intervention group and in the control group at baseline and at the end of the study.

	Intervention Group		Control Group	
	Baseline	Week 8	Baseline	Week 8
Mild obesity	10	7	10	10
Overweight	0	3	0	0

5. Discussion

The results of our study, conducted in patients in primary prevention who, despite following a proper low-fat-low-calorie diet, were overweight or obese and had borderline/abnormal values of the main CV risk factors, suggest that treatment based on a low-GI, soluble plant powder (consisting primarily of cereals, legumes and nut flour), accompanied by a portion of fresh fruit, with the aim of following the principles of a healthy diet, rich in fibers and that provides a good supply of vitamin D, even as part of a low calorie meal could be a feasible therapeutic strategy to improve the results obtained through a low-fat-low-calorie diet alone [3] [5] [6] [7]. In the intervention group, the great majority of overweight subjects lost sufficient body weight to change their BMI classification to become ranged within normal weight (11/16, versus only 2/16 in the control group), while the majority of obese subjects didn't change their BMI classification to enter into lower overweight levels (only 3/10 passed from obese to overweight versus nobody in the control group). This result suggests that in case of obesity a controlled quantitative correction with weighing food portions could be a better strategy than low-calorie replacement meal. Almost all subjects in the intervention group have improved their cardio-metabolic parameters and have reached a high statistically significant reduction in CV risk at 10 years (−20.1% versus −2.3% in the control group). This confirms that reducing risk factor levels in general has a considerable preventive effect on overweight and obese patients, known to be at high CV risk, and also confirms the role of functional foods (so called food that contains substance that provide medical or health benefits). However, the word of functional foods is a “mare magnum”: hundreds have been studied for their supposed/estimated ability to reduce CV risk factors, but only plant sterols at a daily dose of 1.5 - 2 g per day and dietary fibers at a daily dose of at least 3 g per day (we used fibers at dose of 6.4 g per day) are recommended for lowering LDL-cholesterol level [8] [9]. Moreover, data from “The Italian Heart Project” of the Italian Institute of Health have demonstrated that men and women with a 10-year CV risk <20% generate 75% and, respectively, 96% of all events [10]. Therefore, in primary prevention, protecting these categories of patients, in a non-aggressive way, as with functional foods (and nutraceuticals), would bring to a significant reduction in CV events occurring in the population. Finally, a good supply of vitamin D, as part of a healthy diet, not only could help prevent CVD, but also osteoporosis [4]. Further studies are needed to assess long-term effect and compliance of this functional powder.

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