SDRP Journal of Food Science & Technology (ISSN: 2472-6419)

Replacement meal to treat overweight patients

DOI: 10.25177/JFST.3.1.2

Research

March 2018

Received Date: 22nd Feb 2018
Accepted Date: 12th Mar 2018
Published Date:15th Mar 2018

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CONFLICTS OF INTEREST

There are no conflicts of interest for any of the authors.

ABSTRACT

Overweight and obesity are cardiovascular risk factors. Qualitative and quantitative diet and active lifestyle 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 used as replacement meal (for a total calorie intake ranging from a minimum of about 130 kcal to a maximum of 260 kcal) in 50 overweight 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" (25 subjects) versus "control"(25 subjects). After 8 weeks, the treatment based on the replacement meal has improved the results obtained through the qualitative diet alone: 18/25, versus only 5/25 in the control group, became ranged within normal weight. The subjects in the intervention group have improved also their cardiometabolic parameters and consequently have reached a high statistically significant reduction in estimated cardiovascular risk at 10 years.

Keywords: overweight, cardiovascular risk, functional foods, replacement meal

INTRODUCTION

Cardiovascular diseases (CVD) are the leading cause of death in industrialized countries and are an increasingly onerous economic burden on the National Health Service (1,2). Therefore, the identification and treatment of cardiovascular (CV) risk factors is an important, reachable goal (3).

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 (4-6).

The best way to lose weight is to follow a diet and lead an active lifestyle (7). In overweight (and obese) patients, the dietary-nutritional approach must be qualitative (not only reducing fat, but also carbohy-

drate intake, especially simple carbohydrates), and quantitative (eating low-calorie "replacement" meals or weighing food portions) (8).

AIM OF THE STUDY

Assess the effectiveness and tolerability of "IUSVIA", a functional food (so called food that contains substances that provide medical or health benefits) composed of soluble powder rich in fibers and at low glycemic index (GI), used as replacement meal in overweight subjects already in dietary treatment with a qualitative low-fats, low-carbohydrates and low-calories diet.

PATIENTS AND METHODS

This study is part of the programs of workplace medicine ("Pro.Sa." project) in the field of CV health for the staff members of the headquarters of the Italian National Research Council (CNR) of Rome (8,9). Fifty overweight patients, aged >25 and <65 years old, of both genders, in primary CV prevention, with a body mass index (BMI) ≥25.0-<29.9 although following a qualitative low-fats, low-carbohydrates diet (table 1), and already following personal programs of physical activities, were enrolled in a parallel, prospective trial of two randomized sample groups: 25 (14 men and 11 women, average age of 55 years old, 6 smokers, average BMI of 27.6 and waist circumference 93 cm) 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 25 (12 men and 13 women, average age of 56 years old, 5 smokers, average BMI of 27.7 and waist circumference 94 cm) that continued the dietary treatment only, "control group". The informed consent was obtained from all patients before the inclusion in the study.

Table 1 - Overweight (BMI ≥25,0 - 29,9): list of low-fats, low-carbohydrates recommended foods:

- bread, 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 meats (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, cow-mozzarella) *(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)*
- sorbet, jelly, meringue, puddings based on skimmed milk ***
- sugar, jam, marmalade, honey, chestnuts, dried fruit, tinned fruit ***
- nuts: almonds, hazelnuts, peanuts, pistachio, walnuts ***
- 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)*
- wine, beer *(preferably with meals and no more than 1-2 glasses/day)*
- * *Starchy foods and cereals should be consumed daily, but due to high carbohydrate content, amounts should be limited. Moreover, in the same meal, it is better not to mix carbohydrates, meaning do not combine, for example, bread and pasta, bread and rice, bread and potatoes, pasta and potatoes, rice and potatoes.*
- ** *Marine products should be consumed at least 2-3 times per week.*
- *** *Due to high energy content, amount and frequency should be very limited.*
- To achieve a lower fat content, grilling, steaming, boiling, microwaving or barbecuing are preferable methods of cooking. The use of herbs (e.g., basil, mint, parsley, rosemary, sage), garlic, onion, pepper, spices, tomato sauce, mustard, lemon and vinegar is recommended.
- It is important check food labels for fat, sugar and calorie contents of packaged foods.
- Additioning salt to food while cooking or when serving it 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 a week.

Table 2 - Nutritional information **per 100 g** **per 26 g of replacement meal powder**

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
Fibers (g)	25.5	6.6
Proteins (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

The low-calories soluble powder rich in fibers and at low GI used as replacement meal consisted of one dose (two 13 g scoops for a total of 26g, providing 88 kcal) of buckwheat flour, lupin flour, rice fiber, hazelnut flour, carob flour, manna, oat fiber, button mushrooms (Agaricus bisporus), and vitamin D2 (Ergocalciferol) (Table 2), 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.

Exclusion criteria included: a history of CVD, heart failure, liver failure, kidney or lung disease, presence of cancer, known allergy or intolerance to components of the powder.

Visits were carried out at weeks 0 (baseline), 4 and 8 to assess patient compliance, to measure height and body weight 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 (glycemia, insulin, total cholesterol, LDL and HDL cholesterol, triglycerides, and uric acid levels), and safety/tolerability (transaminase and creatinine levels). The 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 calculation of estimated absolute individual CV risk of a CV event over the next 10 years using a computerized programme based on data from the Framingham Heart Study ("Framingham 10 years risk of CVD"), was performed at weeks 0 and 8 (10).

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 $p < 0.05$.

RESULTS

All the patients completed the study without any modifications regarding dietary treatment (low-fats, low-carbohydrates diet), physical activity and smoking habits, and use of drugs for chronic therapies. Tables 3 and 4 contain the effects of the treatments in the intervention group versus control group (in table 3 data are expressed in mg/dL, as mean average and standard deviation, D% versus the baseline). Particularly, in the intervention group, the average BMI passed from 27.7 to 23.7 (-14.4%) versus from 27.6 to 27.0 in the control group (-2.2%), and the waist circumference passed from 94 cm to 83 cm (-11.7%) in the intervention group versus from 93 cm to 92 cm (-2.2%) in the control group. The parameters of the main cardiovascular risk factors (arterial hypertension, hyperlipidemia, diabetes) improved above all in the intervention group versus control group and this reflects the reduction of the estimated CV risk at 10 years that passed from 13,9% to 11.9% (-14.4%) in the intervention group versus from 13.5% to 13.1% (-3.0%) in the control group (table 3).

Table 3 - Effects on cardio-metabolic parameters and on estimated cardiovascular risk at 10 years

	Intervention Group					Control Group				
	Baseline		Week 8			Baseline		Week 8		
	Mean	SD	Mean	SD	Δ%	Mean	SD	Mean	SD	Δ%
Body Mass Index	27.7	9.8	23.7	7.0	-14.4*	27.6	10.2	27.0	8.8	-2.2
Waist circumference (cm)	94	6.8	83	4.9	-11.7*	93	7.4	91	6.6	-2.2
Systolic blood pressure (mmHg)	134	9.1	128	8.2	-4.5	133	7.8	131	7.7	-1.5
Diastolic blood pressure (mmHg)	83	6.3	80	6.1	-3,6	82	6.9	82	6.4	0.0
Total cholesterol (mg/dL)	226	16.1	212	10.0	-6.2*	229	14.8	225	14.6	-1.7
LDL cholesterol (mg/dL)	143	18.6	132	9.8	-7.7*	145	19.1	142	16.2	-2.1
HDL cholesterol (mg/dL)	47	4.3	49	4.4	+4.3	49	4.7	49	4.5	0.0
Triglycerides (mg/dL)	180	28.7	151	16.1	-16.1	174	28.8	166	21.1	-4.6
Gycemia (mg/dL)	103	6.9	99	4.0	-3.9*	102	5.8	101	4.6	-1.0
Insulin (mg/dL)	26	5.7	22	5.3	-15.4*	26	5.8	25	4.8	-3.8
Uric acid (mg/dL)	6.2	1.0	5,9	0.8	-4.8	6.1	0.8	6.0	0.9	-1.6
Cardiovascular risk at 10 years (%)	13.9	5.3	11.9	5.4	-14.4**	13.5	5.2	13.1	5.2	-3.0

*p<0.5 **p<0.01

Table 4 - Effects on body mass index: number of overweight patients

	Intervention Group		Control Group	
	Baseline	Week 8	Baseline	Week 8
Overweight	25	7	25	20

Statistical analysis of the average baseline values of the two groups did not show statistically significant differences. In the patients of the control group, statistical analysis did not show any statistically significant change between week 0 and week 8. On the contrary, 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 several parameters as BMI (-17.6% versus -5.1% in the control group), abdominal circumference (-11.7% versus -4.3% in the control group), total cholesterol (-6.2% versus -1.7% in the control group), LDL-cholesterol (-7.7% versus -2.1% in the control group), glycemia (-3.9% versus -1.0% in the control group), insulin (-15.4% versus -3.8% in the control group), and estimated CV risk (-14.4% versus -3.0% in the control group).

In the intervention group 18/25 (72.0%) overweight subjects passed from overweight to normal weight (versus 5/25, 20.0%, in the control group) (table 4).

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.

DISCUSSION

Our study has been conducted in patients in primary prevention who, despite following a proper qualitative low-fats, low-carbohydrates diet, and personal programs of physical activities (that remained stables during the study) were overweight and had borderline/ abnormal values of the main CV risk factors with a moderate calculated CV risk at 10 years. The results suggest that treatment based on a replacement meal composed of a soluble powder rich in fibers and at low-GI (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, could improve the results obtained through a low-fats, low-carbohydrates diet alone (11.12). By the way, the powder contents also modest but equilibrate quantities of carbohydrates, proteins, pantothenic acid, iron and manganese, not important for the weight management. On the contrary, the right supply of vitamin D contents in the soluble powder not only could help prevent CVD, but also osteoporosis (9).

In the intervention group, most overweight subjects lost sufficient body weight to change their BMI classification to become ranged within normal weight. Therefore, the approach of a functional food used as a replacement meal can be useful in many patients, but not in all: also a controlled quantitative correction with weighing food portions could be a very useful strategy.

Almost all subjects in the intervention group have improved their cardio-metabolic parameters and have reached a high statistically significant reduction in estimated CV risk at 10 years. By the way, data from "The Italian Heart Project" of the Italian Institute of Health have demonstrated that men and women with a 10-year moderate CV risk (<20% at 10 years) generate 75% and, respectively, 96% of all events (13). Therefore, in primary prevention, the treatment to reduce BMI of overweight patients with functional foods would bring to a reduction in CV risk occurring in the population with a moderate CV risk at 10 years (14,15).

ACKNOWLEDGEMENT

Thanks to ESSEDI s.r.l. that has provided IUSVIA, the soluble powder that has been used in our patients as replacement meal.

GRANT

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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