

Low calorie and carbohydrate diet: to improve the cardiovascular risk indicators in overweight or obese adults with prediabetes

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Abstract Our objective was to evaluate the effects of a moderate calorie and carbohydrate-restricted diet on cardiovascular risk indicators in overweight or obese patients with prediabetes. A clinical trial was conducted in which 86 subjects presenting with overweight or obesity and prediabetes received a personalized diet of 1,200 to 1,700 calories with a distribution of 50 % carbohydrates, 20 % proteins, and 30 % fat. Body weight, fat mass, and lean mass were measured through bioimpedance. Glucose, total cholesterol, high density lipoprotein cholesterol and low density cholesterol, and triglycerides were measured. The measurements were taken at the beginning of, and at, 6 and 12 months during the intervention, and the differences were compared by paired Student's *t* and χ^2 tests. At 12 months,

a significant reduction was noticed in body weight in patients with overweight and obesity (72.4 ± 7.8 – 69.6 ± 7.5 kg) (85.7 ± 14.8 – 80.2 ± 12.7 kg) with body mass index (28.2 ± 0.8 – 27.2 ± 2.1 kg/m²) (34.3 ± 3.5 – 32.1 ± 3.2 kg/m²), systolic (120.9 ± 14.2 – 112.4 ± 11.5 mmHg) (124.1 ± 11.9 – 115.7 ± 14.0 mmHg), diastolic blood pressures (79.0 ± 9.3 – 71.8 ± 8.3 mmHg) (80.4 ± 9.0 – 73.7 ± 13.1 mmHg), glucose (106.0 ± 8.9 – 95.9 ± 7.5 mg/dL) (107.3 ± 7.0 – 97.0 ± 8.2 mg/dL), and significant improvement on lipid profile ($p < 0.05$). The restrictions in the calorie and carbohydrate diet decrease the cardiovascular risk indicators in overweight or obese adults with prediabetes.

Keywords Calorie-restricted diet · Carbohydrate-restricted diet · Overweight · Obesity · Prediabetes and cardiovascular risk

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Introduction

In recent years, an increased prevalence in overweight and obesity has been noted at a worldwide level [1]. It is well known that obesity is one of the main elements of metabolic syndrome; as such, it is directly associated to the development of type 2 diabetes, hypertension, cardiovascular disease, and atherosclerotic cerebrovascular disease [2, 3]. It is estimated that 25–50 % of individuals in a prediabetes phase presenting glycosylated hemoglobin values of 5.5–6.5 % can develop type 2 diabetes over the following 5 years unless they receive timely treatment [4]. Intensive strategy studies geared toward modifications in lifestyle have reduced the rate of diabetes in individuals with risk factors and have even prevented the onset of diabetes in up to 58 % [5]. Furthermore, being overweight

could be related with metabolic syndrome illnesses such as non-alcoholic fatty liver disease (NAFLD) [6].

The importance of nutritional therapy in the treatment of overweight and obesity is a well-known fact. At present, there have been various nutritional strategies proposed, primarily addressing the issue of weight loss; these underscore calorie restrictions or changes in carbohydrates, protein, or fat content. The effect of low carbohydrate diets has been linked to the loss of body weight 6 months after the intervention. Nonetheless, the effect of the said diets after 12 months does not show conclusive results [7, 8]. At the same time, this diet is linked to improved cardiovascular risk markers in obese patients. However, long-term adherence is limited [9–11].

Calorie restriction overall is known to improve glucose levels independently of body weight loss in obese patients [12], while even a modest 5–10 % weight loss is associated with lower insulin resistance and hence the development of type 2 diabetes [13–15]. Some authors have noted a greater loss in body mass index (BMI) with a low carbohydrate and high fat diet. Nevertheless, an increase in lipid levels is observed, thus increasing the risk of cardiovascular disease [15–18]. Two recent meta-analyses suggest that low carbohydrate diets are efficacious in reducing body weight at 6 months with a modest impact on total cholesterol, triglycerides, and low density lipoproteins (LDL-C) [19, 20]. On the other hand, a systematic review has not identified these findings [21, 22].

While the benefit of a calorie- and carbohydrate-restricted diet on body weight loss of obese patients has already been established, the same effect is not noted for cardiovascular risk indicators. Although nutritional therapy is a very important element in the management of obesity—and even more so when the obese patient presents alterations in carbohydrate metabolism—we must evaluate strategies geared to having an effect on metabolic risk indicators to bring down the diabetes rate in metabolic risk patients. Given the foregoing information, the objective of this paper is to evaluate the effect of a personalized diet centering on moderate calorie and carbohydrate restrictions on cardiovascular risk indicators in patients with overweight or obesity and prediabetes.

Patients and methods

A clinical trial was carried out from February 2009 through November 2010 in patients with obesity and prediabetes. The patients were selected from a national multi-center study called “*Prevention and early treatment of Type 2 diabetes mellitus*,” conducted in 11 cities throughout Mexico. A random sampling of 1,000 individuals registered at a family medicine unit in Mexico City was taken

from the population base of the Mexican Social Security Institute (the largest social security institution in the country, covering half of the country’s population). Pregnant women, type 2 diabetics, and individuals with hypothyroidism, Cushing syndrome, or presenting polycystic ovary or hypogonadism were not included, neither were individuals with any current prescriptions for obesity or dyslipidemia. Hypertensive patients were included and if treated, they continued with their medication. The Institutional Review Board approved this study. Participating patients signed an informed consent form prior to the study.

Cardiovascular risk indicators

The study comprised 86 patients classified with overweight or obesity status which was assessed using a BMI according to the World Health Organization (WHO) [23]. Prediabetes was identified when patients registered impaired fasting glucose (fasting blood glucose between 100 and 125 mg/dL) or glucose intolerance (blood glucose between 140 and 199 mg/dL 2 h after a 75 g oral glucose load). Hypertension was determined when systolic pressure was greater than 130 mmHg or diastolic pressure was greater than 85 mmHg, or when the patient took a hypertension drug regardless of blood pressure reading. Metabolic syndrome was determined when the patient presented two or more of these parameters: systolic blood pressure ≥ 130 mmHg or diastolic ≥ 85 mmHg, fasting glucose ≥ 120 mg/dL, triglycerides ≥ 150 mg/dL or high density lipoproteins (HDL-C) < 40 mg/dL in men and < 50 mg/dL in women for all subjects with a waist circumference ≥ 90 cm in men or ≥ 80 cm in women, according to criteria established by the International Diabetes Federation [24].

Clinical and anthropometric measurements

At the beginning of the study, a medical history, physical examination, and family background record on type 2 diabetes, cardiovascular disease, and obesity was taken for each participant, in addition to socio-demographic indicators. Systolic and diastolic blood pressure was measured on three occasions with a mercury sphygmomanometer after the patient had been seated for at least 15 min. The second and third measurements were averaged and this average was used for analysis. Anthropometry was recorded by the registered dietitians and previously standardized using the method proposed by Habitch and in keeping with the specifications recommended by Lohman et al. [25, 26].

Body weight and height were measured using a TANITA™ scales model TBF-215, which in addition provided information on fat percentage, body fat mass in kilograms and lean mass through lower segment bioimpedance analysis. Waist circumference was measured after determining

the midpoint between the lowest rib and the upper edge of the iliac crest on the right side. Hip circumference was determined through the diameter of the great trochanters. Both measurements were taken on three occasions and the average of the second and third measurement was used for analysis purposes.

Biochemical specifications

Following a 12-h fast, blood plasma values were taken to determine concentrations of glucose, insulin, total cholesterol, HDL-C, and triglycerides by means of the enzyme method with a RocheTM/Hitachi 904/911/917: ACN 249; ACN 407 analyzer (R2 application). LDL-C was calculated by means of the Friedewald formula ($\text{LDL-C} = \text{total cholesterol} - (\text{triglycerides}/5) - \text{HDL-C}$) [27]. Two hours after an oral load of 75 g of glucose has been administered, both glucose and insulin were measured (the latter through radio immunoanalysis). Insulin resistance was calculated through the homeostatic model assessment (HOMA) score by means of the formula ($\text{HOMA}_{\text{IR}} = \text{fasting insulin } (\mu\text{UI/dL}) \times \text{glucose (mmol/L)}/22.18$) [28]. After 6 and 12 months of follow-up, measurements of glucose, total cholesterol, HDL-C, LDL-C, and triglycerides were repeated.

Nutritional intervention

At the basal stage, a semi-quantitative questionnaire on the frequency of food consumption was applied and a reminder issued to list foodstuffs ingested in a 24-h period in order to identify the customary diet, tastes, habits, and food preferences of the patient. The intervention followed the guidelines indicated by the consensus for treatment of obesity [29, 30]. One month prior to the intervention, patients received training to identify and quantify the calorie content of different groups of food as well as on the importance of a healthful diet, including reduced ingestion of saturated fats and simple sugars. A minimum consumption of 25 g of fiber a day was suggested, pursuant to the WHO proposal for adults [31, 32]. Following the month of training and standardization, patients received an individualized diet where gender, occupation, schooling, eating habits, tastes, and habits were considered. At the same time, meal schedules at home and at work were advised with suggestions to exchange some food items for healthful choices as convenient for the occupation in question. Calorie consumption for women fluctuated between 1,200 and 1,400 calories and for men between 1,500 and 1,700 calories. The dietary plan took into account an average restriction of 500 calories as per the Harris Benedict formula to calculate basal metabolism and in keeping with the

United Nations Food and Agriculture Organization and the WHO guidelines for physical activity [33, 34].

The proportion of carbohydrates was reduced to 50 % and protein intake was recommended at 20 % with a suggested consumption of both animal and plant origin. As concerns fat, distribution was equal or less than 30 % of the total caloric intake. Ten percent was assigned to saturated fatty acids and 20 % to monounsaturated and polyunsaturated fatty acids. Fiber intake following the month of training was recommended at 25 g/day, either soluble or insoluble fiber, particularly found in whole grains such as oats, wheat germ, fruits, and green vegetables. Increased consumption of white meats was recommended with consumption of red meats limited to twice a week. It was also suggested that low fat cheese and dairy products be selected. Each patient received training on how to count carbohydrates and calories consumed in the various portions for all different groups of food, in keeping with the Mexican System for Food Equivalencies [29]. Four to five rations of cereals per day were suggested. Simple sugars in limited amounts and non-nutritional sweeteners were suggested for use. In order to promote improved adherence to the diet, various menus were drawn up based on the aforementioned specifications. Every month, the patients received a different menu, and the food log that was kept 24 h a day helped identify obstacles and questions regarding the diet. This was used to indicate to patients the appropriate consumption of calories and carbohydrates. All participants received instructions to practice an aerobic exercise of moderate intensity for at least 30 min three times a week.

A patient was considered to have kept to the nutritional intervention when he or she attended at least 80 % of scheduled appointments. These appointments were scheduled on a monthly basis for 12 months of the intervention. The average length of each control or checkup appointment fluctuated between 30 and 40 min, wherein measurements of body weight, waist circumference, and blood pressure were taken to encourage the patient to continue with the nutritional therapy program.

Statistical analysis

Basal characteristics of patients were analyzed through estimating measurements on central tendency (average and standard deviation) and proportions. In order to measure the effect of the body weight intervention, BMI, fat percentage, waist and hip circumference, fat mass, and skin folds, as well as other variables including glucose, triglycerides, total cholesterol, HDL-C, and LDL-C, were measured by the paired Student's *t* test. χ^2 tests were used to identify changes in the components of metabolic

syndrome in patients presenting obesity and prediabetes at the conclusion of the intervention.

Results

Ninety-nine individuals complied with the inclusion criteria for the study. Of these, seven decided not to participate because they considered that they did not have the time to attend control appointments and six did not comply with the minimum of 80 % of scheduled visits. Table 1 describes the basal characteristics of the 86 patients who concluded the 12-month intervention. The study comprised 86 subjects, 47 were women and 39 were men. A higher number of subjects with intermediate level schooling were noted, and 76 % of the population was employed. Forty-three patients had obesity and 43 overweight. Eighteen patients (21 %) had arterial hypertension at the beginning of the study, 53 % were glucose intolerant, and 58 % were insulin resistant according to the $HOMA_{IR} \geq 2.5$ score. The

Table 1 Baseline characteristics of patients with overweight or obesity and prediabetes included in the study

<i>n</i> = 86		
	<i>n</i>	%
Sex		
Female	47	55
Male	39	45
Age	Mean ± SD	
Years	49 ± 10.04	
School level		
Basic	32	37
Intermediate	35	41
Advanced	19	22
Occupation		
Employee	65	76
Household, commerce, retired, or other	21	24
Comorbidity		
Overweight	43	50
Obesity	43	50
Hypertension	18	21
Glucose intolerance	48	53
$HOMA_{IR} \geq 2.5$	50	58
Family history		
Diabetes	49	57
Obesity	55	64
Hypertension	52	60
Cardiovascular disease	29	34

Data are shown as absolute and relative frequencies, mean ± SD
 $HOMA_{IR}$ homeostatic model to assess insulin resistance

main diseases found in the family background were diabetes, rising to 57 %, obesity at 64 %, arterial hypertension in 60 % of cases, and 34 % with a family history of cardiovascular disease.

Effect of diet on anthropometric indicators

Tables 2 and 3 show the changes in anthropometric indicators after 6 and 12 months of intervention in patients with overweight and obesity. A significant drop was noted in body weight, BMI, waist and hip measurements, and in the percentage of fat and fatty mass compared to the basal indicators.

As regards blood pressure readings, a significant drop was noted in systolic blood pressure after 6 and 12 months on the intervention, as was also the case for diastolic blood pressure compared to the basal indicators.

After 6 and 12 months of follow-up, significant changes were found only in waist circumference. In the case of patients with obesity, significant changes were found in the BMI and waist circumference.

Effects of the intervention on metabolic indicators

With regard to metabolic indicators in patients with overweight and obesity, there was a marked reduction in glucose, triglyceride, total cholesterol, and LDL-C levels after 6 and 12 months compared to the initial measurements; at the same time, a significant increase was noted in HDL-C.

After 6 and 12 months, we observed improvement in the levels of glucose, triglycerides, and total cholesterol in both groups and only in patients with obesity, we observed an improvement in LDL-C.

Table 4 shows the modification of metabolic syndrome components. A significant reduction was noted in the frequency of each of the components except for glucose. This modification in indicators was maintained for the 6 and 12 months of follow-up. Notable changes were recorded for abdominal obesity, arterial hypertension, hyperglycemia, hypertriglyceridemia, and hypo- α -lipoproteinemia. Lastly, a reduction was noted in metabolic syndrome from 77.9 to 29.1 % at 12 months after the intervention (p 0.005).

Discussion

The results of this study indicate that a moderately restricted calorie and carbohydrate diet has a positive effect on body weight loss and improves the elements of metabolic syndrome in patients with overweight or obesity and prediabetes. These results underscore the need to provide dietary recommendations focusing on calorie and carbohydrate restrictions and encouraging increased

Table 2 Effect of intervention on anthropometric, clinical, and metabolic data in patients with overweight at 6 and 12 months

<i>n</i> = 43	Baseline		6 months		12 months		Δ Baseline versus 6 months			Δ Baseline versus 12 months			Δ 6 versus 12 months		
	Mean ± SD	SD	Mean ± SD	SD	Mean ± SD	SD	Mean difference	95 % Confidence intervals	<i>p</i> *	Mean difference	95 % Confidence intervals	<i>p</i> *	Mean difference	95 % Confidence intervals	<i>p</i> *
Anthropometric data															
Weight (kg)	72.4 ± 7.8		69.9 ± 7.6		69.6 ± 7.5		-2.5	-1.5 to -3.4	0.001	-2.8	-1.3 to -4.32	0.001	-0.3	-0.8 to -1.4	0.572
BMI (kg/m ²)	28.2 ± 0.8		27.2 ± 1.1		27.2 ± 2.1		-0.9	-0.6 to -1.3	0.001	-1.0	-0.43 to -1.6	0.001	0.07	-0.4 to -0.5	0.762
Waist (cm)	92.8 ± 6.1		89.9 ± 5.9		89.4 ± 5.7		-2.8	-1.7 to -4.0	0.001	-3.3	-1.9 to -4.7	0.001	-0.5	-0.5 to -1.6	0.038
Hip (cm)	101.1 ± 3.9		99.6 ± 5.2		99.6 ± 4.8		-1.5	-0.2 to -2.8	0.025	-1.5	-0.5 to -2.5	0.004	-0.1	-1.2 to -1.2	0.983
Fat percentage	33.3 ± 5.3		31.2 ± 6.3		30.6 ± 6.2		-2.1	-0.6 to -3.5	0.006	-2.6	-1.6 to -3.5	0.001	-0.5	-0.6 to -1.6	0.377
Fat mass (kg)	24.1 ± 9.5		21.7 ± 4.5		21.3 ± 4.5		-2.4	-1.2 to -3.5	0.001	-2.7	-1.8 to -3.7	0.001	-0.3	-0.3 to -1.0	0.326
Lean mass (kg)	48.8 ± 8.0		48.2 ± 7.8		48.6 ± 8.0		-0.6	-0.7 to -1.9	0.368	-0.2	-0.2 to -0.7	0.373	-0.9	-1.9 to -19.0	0.107
Blood pressure (mmHg)															
Systolic	120.9 ± 14.2		115.3 ± 11.1		112.4 ± 11.5		-5.6	-1.9 to -9.3	0.004	-8.5	-3.8 to -13.1	0.001	-2.8	-0.7 to -6.4	0.359
Diastolic	79.0 ± 9.3		72.9 ± 6.3		71.8 ± 8.3		-6.1	-3.7 to -8.5	0.001	-7.2	-3.9 to -10.6	0.001	-1.0	-1.6 to -3.8	0.425
Metabolic (mg/dL)															
Glucose	106.0 ± 8.9		100.5 ± 10.0		95.9 ± 7.5		-5.4	-2.5 to -8.4	0.001	-10.2	-7.4 to -12.7	0.001	-4.6	-2.0 to -7.1	0.001
Triglycerides	217.1 ± 156.3		183.5 ± 100.6		154.7 ± 66.2		-33.5	-0.06 to -67.2	0.050	-62.3	-18.5 to -106.1	0.006	-28.7	-4.8 to -52.6	0.020
Total cholesterol	212.5 ± 51.4		194.1 ± 48.8		180.2 ± 35.8		-18.4	-6.9 to -29.9	0.002	-28.7	-20.8 to -36.6	0.001	-13.8	-2.9 to -24.8	0.014
HDL-C	38.8 ± 9.2		44.1 ± 12.7		44.6 ± 12.7		5.2	1.5 to 8.8	0.006	5.5	2.9 to 8.1	0.001	0.9	1.2 to 3.0	0.402
LDL-C	128.3 ± 46.6		112.3 ± 44.8		104.8 ± 31.3		-15.9	-5.3 to -26.4	0.004	-24.6	-12.9 to -36.2	0.001	-8.5	-1.9 to -19.0	0.107

Δ Change magnitude

* Paired Student's *t* test

Table 3 Effect of intervention on anthropometric, clinical, and metabolic data in patients with obesity at 6 and 12 months

<i>n</i> = 43	Baseline		6 months		12 months		Δ Baseline versus 6 months			Δ Baseline versus 12 months			Δ 6 versus 12 months		
	Mean ± SD	SD	Mean ± SD	SD	Mean ± SD	SD	Mean difference	95 % Confidence intervals	<i>p</i> *	Mean difference	95 % Confidence intervals	<i>p</i> *	Mean difference	95 % Confidence intervals	<i>p</i> *
Obesity anthropometric data															
Weight (kg)	85.7 ± 14.8		82.3 ± 14.9		80.2 ± 12.7		3.3	-2.2 to -4.4	0.001	-5.4	-4.0 to -6.8	0.001	-2.1	-0.4 to -3.8	0.017
BMI (kg/m ²)	34.3 ± 3.5		33.0 ± 4.0		32.1 ± 3.2		-1.3	-1.7 to -5.9	0.001	-2.1	-1.6 to -2.6	0.001	-0.8	-1.5 to -2.3	0.024
Waist (cm)	105.8 ± 12.0		100.7 ± 9.7		98.9 ± 8.4		-5.0	-2.4 to -7.6	0.001	6.9	-3.9 to -9.8	0.001	-1.8	-0.1 to -3.8	0.065
Hip (cm)	114.4 ± 9.6		112.2 ± 9.8		111.5 ± 9.6		-2.1	-0.3 to -4.0	0.022	-2.8	-1.3 to -4.4	0.001	-0.7	-1.1 to -2.5	0.443
Fat percentage	41.2 ± 5.7		39.6 ± 6.0		38.9 ± 6.4		-1.6	-0.7 to -2.5	0.001	-2.3	-1.2 to -3.5	0.001	-0.7	-0.3 to -1.8	0.185
Fat mass (kg)	35.6 ± 9.5		33.1 ± 9.2		32.7 ± 9.2		-2.4	-1.4 to -3.3	0.001	-2.8	-1.5 to -4.1	0.001	-0.3	-0.7 to -1.5	0.492
Lean mass (kg)	50.1 ± 8.4		49.7 ± 8.6		48.7 ± 8.7		-0.3	-0.5 to -1.1	0.439	-1.3	-0.1 to -2.8	0.780	-1.0	-0.4 to -2.5	0.173
Blood pressure (mmHg)															
Systolic	124.1 ± 11.9		118.2 ± 11.3		115.7 ± 14.0		-5.9	-2.8 to -8.9	0.001	-8.3	-4.5 to -12.2	0.001	-2.4	-1.6 to -6.6	0.236
Diastolic	80.4 ± 9.0		74.8 ± 7.8		73.7 ± 13.1		-5.6	-3.0 to -8.1	0.001	-6.6	-2.9 to -10.4	0.001	-1.0	-2.7 to -4.9	0.570
Metabolic (mg/dL)															
Glucose	107.3 ± 7.0		100.6 ± 8.0		97.0 ± 8.2		-6.7	-3.9 to -9.5	0.001	-10.3	-7.2 to -13.3	0.001	-3.5	-0.9 to -6.2	0.009
Triglycerides	198.4 ± 101.7		173.0 ± 72.4		144.7 ± 44.9		-25.3	-2.8 to -47.8	0.028	-53.6	-25.4 to -81.9	0.001	-28.3	-9.9 to -46.7	0.003
Total Cholesterol	207.3 ± 46.6		196.4 ± 41.2		182.3 ± 36.9		-10.9	-3.7 to -18.0	0.004	-25.0	-16.1 to -33.8	0.001	-14.0	-7.0 to -21.1	0.001
HDL-C	40.0 ± 11.5		43.4 ± 10.0		44.8 ± 11.4		3.3	1.0 to 5.7	0.006	4.7	1.4 to 8.1	0.007	1.3	1.4 to 2.1	0.329
LDL-C	127.6 ± 35.1		118.4 ± 34.7		108.6 ± 30.0		-9.2	-1.3 to -17.1	0.023	-19.0	-10.8 to -27.2	0.001	-9.8	-3.0 to -16.5	0.006

Δ Change magnitude

* Paired Student's *t* test

Table 4 Change in the components of the metabolic syndrome in patients with overweight or obesity and prediabetes

	Baseline %	6 months %	12 months %	p^1 %	p^2 %	p^3 %
Abdominal obesity ^a	64.0	50.0	45.4	0.001	0.001	0.001
Systolic ≥ 130 mmHg	37.2	15.1	18.6	0.001	0.081	0.006
Diastolic ≥ 85 mmHg	20.9	7.0	9.3	0.004	0.223	0.001
Glucose ≥ 100 mg/dL	81.4	46.5	31.4	0.175	0.541	0.001
Triglycerides ≥ 150 mg/dL	66.3	53.5	36.1	0.001	0.034	0.004
HDL-C ≤ 40 mg/dL	72.1	53.5	47.7	0.001	0.001	0.001
Metabolic syndrome	77.9	40.7	29.1	0.148	0.149	0.005

¹ χ^2 p value (Baseline vs 6 months)² χ^2 p value (Baseline vs 12 months)³ χ^2 p value (6 vs 12 months)^a ≥ 102 in men and ≥ 88 cm in females

consumption of animal and plant protein. Other authors have obtained similar results after 4 months of intervention with a diet high in protein and low in carbohydrates resulting in body weight loss. Nonetheless, they did not note significant differences in other metabolic indicators such as those observed in this study [35]. It has been reported that a low carbohydrate diet together with behavioral therapy produces efficacious body weight loss and improves early malfunctioning of the cardiovascular system [36]. Our results are in agreement with reports produced by other authors who also assessed a carbohydrate-reduced diet, and noted an 11 % drop in body weight in a follow-up after 1 year and 7 % at 2 years. On the other hand, the differences noted in triglycerides, blood pressure figures, and LDL-C were significant only at 6 months and were not maintained after 12 months following the intervention [37]. High LDL-C levels are strongly associated with developing carotid atherosclerosis in patients with metabolic syndrome [38]. Even though our intervention achieved the reduction of LDL-C after 6 months in this indicator, we consider it important to achieve normal levels of LDL-C for a long time; an integral treatment including modifying lifestyle and pharmacological treatment to prevent cardiovascular disease is necessary. The results of our study are similar to those presented by Frisch and colleagues, who compared patients presenting obesity on a low carbohydrate diet to those on a low fat diet; after 6 months they found improved triglyceride and HDL-C (p 0.005) levels. Nonetheless, as in the aforementioned study, after 12 months, the low carbohydrate diet only had an impact on the waist circumference (p 0.037) and on blood pressure figures (p < 0.007) when compared to the low fat diet [39].

It has been proposed that a low carbohydrate diet has a better effect on reducing body weight and on glycemic control in patients with obesity, diabetes, or metabolic

syndrome as compared to a conventional calorie-restricted diet [7]. In this regard, it is important to underscore that the intervention focused on subjects who in addition to presenting obesity also had glucose alterations or prediabetes as risk factors for the development of type 2 diabetes, underscoring the importance of our results that show a clinical change at 6 and 12 months during follow-up. At the same time, it was important to note that the proportion of patients with glucose at ≥ 100 mg/dL—which at the beginning of our study stood at 81.4 %, and after 6 months of intervention was reduced by half—at the end of the follow-up was only 31.4 %. These results are clinically important owing to the significant decrease in the proportion of patients with prediabetes. Also worth noting is that during follow-up, the rate of diabetes stood at zero—results that are comparable to those obtained through nutritional therapy and treatment with medication [40–42]. The findings presented in this study are similar to those observed in the Diabetes Prevention Program where the most significant decrease in the rate of diabetes in adults with prediabetes who received intensive treatment geared toward changing lifestyle (diet and exercise) was noted as compared to those who received treatment through medication [43]. The benefits of the carbohydrate and fat reduction diet to improve the insulin resistance and other associated diseases of dyslipidemia and obesity such as NAFLD characterized by hepatocyte injury and inflammation [44] are known.

In the same manner, we noted a significant reduction in the percentage of total fat and waist circumference—indicators directly associated with insulin resistance or increased cardiovascular risk [41]. Another proven important element to achieve a greater effect in other cardiovascular risk indicators is physical exercise [45]. In this regard, although the patients assessed received specific recommendations on aerobic exercise, only 10 % of

patients actually exercised regularly (data not shown); hence, we consider that the greatest effect is owed to nutritional intervention. It is recognized that physical activity is the main component to improve indicators of metabolic syndrome [46]. However, in our study, a limited number of patients mentioned following a physical activity plan; jogging, dancing, and walking were mentioned as the most frequent physical activity performed.

On the other hand, it is well known that arterial hypertension is linked increasingly to coronary and cardiovascular disease. The significant, sustained decrease in the arterial hypertension figures following 6 and 12 months of intervention underscores the benefits of combining nutritional therapy and medication to control this health problem and thus reduce the risk of cardiovascular complications. This is a conclusion that we share with other authors who have had similar results when drug therapy is used in conjunction with dietary interventions [47].

Although obesity is the most related issue associated to the metabolic syndrome, this syndrome is the main predictor for type 2 diabetes and cardiovascular disease. It is important that a timely intervention is done, geared to the lifestyle modification in individuals with overweight, being that they could have alterations in glucose, lipids, and blood pressure as the population studied did. At the beginning of this study, patients with overweight as well as those with obesity showed alterations in glucose and in the lipids' profile.

Some of the limitations our study faced included not having an explicit control group. However, in this type of study, the subject himself or herself becomes his or her own control, based on the premise that over time, the end variables studied will not be affected, and the variability of the subjects—owed to confounders—is controlled. As has been said, patients presenting obesity show limited observance of a nutritional treatment [48–50]. In this regard, we believe that personalized nutritional education is needed in order to attain better control and observance of non-medication-based treatment for patients with obesity.

By way of conclusion, our results confirm that an intervention with moderately restricted calories and carbohydrates reduces body weight. In addition, it offers comprehensive, personalized dietary advice, improves cardiovascular risk indicators, and the weight loss is maintained 1 year in the follow-up of patients with overweight or obesity and prediabetes.

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intervention presented herein was carried in strict accordance to the General Health Law and Regulation in the Field of Clinical Research in Mexico about good clinical practice in clinical trials. Respecting the patients and their welfare right was considered a priority during the study. According to aforementioned laws, this study constitutes a minimal risk research.

Conflict of interest As authors of this manuscript, we state that there is no conflict of interest in any particular form, and that this research was carried out with the financial support provided by the Coordination of Health Research belonging to the Mexican Institute of Social Security.

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