



## Effect of Low Carbohydrate Diet Versus Low Fat Diet on Body Health: A Randomized Controlled Trials

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### ABSTRACT

**Introduction:** Squeal of obesity in the adolescent population includes immediate biochemical abnormalities or disease including dyslipidemia, insulin resistance, impaired glucose tolerance, and type 2 diabetes mellitus.

**Materials & Methods:** During an enrollment period 150 subjects were randomly assigned to either the low-carbohydrate diet or the low-fat diet, with use of a pre-established algorithm generated from a random set of numbers.

**Results & Conclusion:** Our findings demonstrate that severely obese subjects with a high prevalence of diabetes and the metabolic syndrome lost more weight during six months on a carbohydrate restricted diet than on a calorie- and fat-restricted diet.

### KEYWORDS

Low Carbohydrate, Fat Diet, Body Health, Trials

### Introduction

In the past 4 decades, the prevalence of obesity among adults aged 20 to 74 years in the united states increased from 13% to 31%. In the United States, obesity results in an estimated 325000 deaths annually and accounts for about 5.5% of total direct health care costs.<sup>1</sup> At any given time, approximately 45% of women and 30% of men in the United States are attempting to lose weight.<sup>2</sup> Numerous diets have been proposed to promote weight loss. Weight loss from certain diets may lead to prevention of type 2 diabetes and improved control of hypertension and may reduce cardiovascular morbidity and mortality.<sup>3,4</sup>

Squeal of obesity in the adolescent population include immediate biochemical abnormalities or disease including dyslipidemia, insulin resistance, impaired glucose tolerance, and type 2 diabetes mellitus.<sup>5</sup>

Recently diets low in carbohydrate (low-CHO diets) have become the focus of international attention since the recent WHO recommendations to reduce the overall consumption of sugars and some health professionals recommendations to reduce the consumption of rapidly digestible starches that lead to high glycaemic responses.<sup>6, 7</sup> While both low-carbohydrate and low-fat diets can lead to weight loss and have a beneficial effect on CVD risk profile, there may be different mechanisms by which the diets and weight loss on these diets potentially reduces CVD risk. <sup>8,9</sup>

The reported effects of a carbohydrate-restricted diet on risk factors for atherosclerosis have varied. We performed a study designed to test the hypothesis that severely obese subjects with a high prevalence of diabetes or the metabolic syndrome would have a greater weight loss, without detrimental effects on risk factors for atherosclerosis, while on a carbohydrate-restricted (low-carbohydrate) diet than on a calorie- and fat-restricted (low-fat) die.

### Materials & Methods

During an enrollment period 150 subjects were randomly assigned to either the low-carbohydrate diet or the low-fat diet, with use of a pre-established algorithm generated from a random set of numbers. We used stratified randomization, with blocking within strata, to ensure that each group would contain approximately equal numbers of women, subjects with diabetes, and severely obese subjects.

The study was approved by the institutional review board and an approved consent form was signed by each subject. Inclusion criteria were an age of at least 18 years and a body-mass index of at least 35. Exclusion; hepatic disease; severe, life-limiting medical illness; inability of diabetic subjects to monitor their own glucose levels; active participation in a dietary program; or use of weight loss medications.

The two diet groups attended separate two-hour group-teaching sessions each week for four weeks, followed by monthly one-hour sessions for five additional months; all sessions were led by experts in nutritional counseling. Subjects received a diet overview handout, instructional nutrition labels, sample menus and recipes, and a book on counting calories and carbohydrates. No specific exercise program was recommended. The subjects assigned to the low-carbohydrate diet were instructed to restrict carbohydrate intake to 30 g per day or less. No instruction on restricting total fat intake was provided. Vegetables and fruits with high ratios of fiber to carbohydrate were recommended. The subjects' weights were measured monthly on a single calibrated scale. Other data collected at enrollment and at six months included waist size, self-reported medical history, blood pressure, and glucose and serum lipid levels, measured in blood specimens obtained after an overnight fast

### Statistical analysis

The primary end point was weight loss at six months. Assuming a two-sided type I error of 5 percent, we estimated that we would need 100 subjects (50 per group) for the study to have 80 percent power to demonstrate a mean ( $\pm$ SD) weight loss that was  $5\pm 12$  kg greater in the low-carbohydrate group than in the low-fat group. Given an anticipated dropout rate of 25 percent, we set the enrollment target at 150 subjects. By six months, 90 subjects remained in the study (47 in the low-fat group and 43 in the low-carbohydrate group).

For analyses of changes in dietary intake, serum lipid levels, glycemic control, we included all subjects, with base-line values carried forward for subjects who dropped out of the study. For comparison of continuous variables between the two groups, we calculated the change from base line to six months in each subject and compared the mean changes in the two diet groups using an unpaired t-test. We assessed the normality of the distribution of all variables before using the t-test. Triglyceride and glucose levels were skewed and were

therefore log-transformed for analysis. Dichotomous variables were compared by chi-square analysis. Linear regression and two way analysis of covariance models were used to correct for potentially confounding variables and to identify interactions between variables and diet group assignment. Missing waist sizes were imputed by linear extrapolation on the basis of height and weight. P value of 0.05 or less was considered to indicate statistical significance. Analyses were performed with use of SPSS software (version 10.0).

**Results**

Subjects in the two groups were well matched with regard to base-line characteristics (Table 1). The subjects were severely obese at base line (Table 1), with a high prevalence of diabetes (39 percent) or the metabolic syndrome without diabetes (43 percent), as previously defined. The cumulative percentage of subjects who dropped out of the study by months 1, 3, and 6 were 38, 44, and 47 percent, respectively, in the low-fat group and 25, 27, and 33 percent, respectively, in the low-carbohydrate group. Differences in attrition between groups were statistically significant by the third month (P=0.03) but were not significant at six months (P=0.10). There were no significant differences between the groups in the characteristics of the subjects who dropped out of the study (Table 2). Subjects on the low-carbohydrate diet attended more dietary counseling sessions than did the subjects on the low-fat diet (mean, 5.7±2.7 vs. 4.3 ±2.7; P=0.006).

After six months of dietary counseling, subjects on the low-fat diet reported a decrease in caloric consumption while their macronutrient composition was close to the guidelines of the National Heart, Lung, and Blood Institute (Table 2).<sup>7</sup> As compared with the subjects on the low-fat diet, subjects on the low-carbohydrate diet reported a non-significantly greater reduction in caloric intake (P=0.33), a significantly greater decrease in the percentage of calories from carbohydrates.

Subjects on the low-carbohydrate diet lost more weight during the six-month study than did those on the low-fat diet (mean, -5.8±8.6 kg vs. -1.9± 4.2 kg; 95 percent confidence interval for the difference in weight loss between groups, -1.6 to -6.3; P=0.002). The difference in weight loss between the groups remained significant after adjustment for base-line variables alone (age, race or ethnic group, sex, base-line body-mass index, baseline caloric intake, and the presence or absence of hypertension, diabetes, active smoking, and sleep apnea) (P=0.002) and for base-line variables plus the number of dietary counseling sessions attended (P=0.01).

During the six-month study, there was a greater decrease in the mean triglyceride level in the low-carbohydrate group than in the low-fat group (-20±43 percent vs. -4±31 percent, P=0.001) (Table 3). This difference remained significant after adjustment for base-line variables.

**Discussion**

We found that severely obese subjects with a high prevalence of diabetes and the metabolic syndrome lost more weight in a six-month period on a carbohydrate-restricted diet than on a fat- and calorierestricted diet. The greater weight loss in the lowcarbohydrate group suggests a greater reduction in overall caloric intake, rather than a direct effect of macronutrient composition. However, the explanation for this difference is not clear. Subjects in this group may have experienced greater satiety on a diet with liberal proportions of protein and fat. However, other potential explanations include the simplicity of the diet and improved compliance related to the novelty of the diet. Subjects in the low-carbohydrate group had greater decreases in triglyceride levels than did subjects in the low-fat group; and subjects with diabetes on this diet had a greater improvement in glycemic control. No adverse effects on other serum lipid levels were observed. Most studies suggest that lowering triglyceride levels has an overall cardiovascular benefit.

Taken together, our findings demonstrate that severely obese subjects with a high prevalence of diabetes and the metabolic syndrome lost more weight during six months on a carbohydrate restricted diet than on a calorie- and fat-restricted diet. The carbohydrate-restricted diet led to greater improvements in insulin sensitivity that were independent of weight loss and a greater reduction in triglyceride levels in subjects who lost more than 5 percent of their base-line weight. These findings must be interpreted with caution, however, since the magnitude of the overall weight loss relative to our subjects' severe obesity was small, and it is unclear whether these benefits of a carbohydrate-restricted diet extend beyond six months. Furthermore, the high dropout rate and the small overall weight loss demonstrate that dietary adherence was relatively low in both diet groups.

**Table 1: Base line characteristics of the subjects**

Characteristics	Low Carbohydrate Diet	Low Fat Diet
Age (yr)	55 years	58 years
Body mass Index	43.9	44.8
Weight (kg)	110	120
Female	20	25
Male	70	65
Systolic Blood Pressure (mm, Hg)	130	135
Diastolic Blood Pressure (mm, Hg)	75	80

**Table 2: Changes from baseline in the composition of the two diets**

Variable	Base line	P value	6 months	P value
Total Calorie per day	1900 2100	0.30	1500 1600	0.33
Protein	18 19	0.4	2 8	<0.001
Carbohydrate	55 48	0.5	55 35	<0.001
Fat	35 35	0.77	1 9	0.004

**Table 3. Changes from base line in serum lipid**

Variables	Base line	P value	6 months	P value
Triglyceride (mg/dl)	177 189	0.7	170 145	0.001
Total Cholesterol (mg/dl)	200 175	0.15	190 180	0.53
High Density Lipoprotein cholesterol (mg/dl)	41 42	0.77	40 42	0.56
Low Density Lipoprotein cholesterol (mg/dl)	119 115	0.6	121 115	0.8

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