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Comparative Study of a One Year Dietary Intervention of a Low-Carbohydrate to a Low-Fat Diet on Weight and Glycemic Control in Type 2 Diabetes

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Objective: To compare the effects of a one year intervention with a low-carbohydrate and a low-fat diet on weight loss and glycemic control in patients with type 2 diabetes.

Methods: This study is a randomized clinical trial of 105 overweight adults with type 2 diabetes. Primary outcomes were weight and A1c. Secondary outcomes included blood pressure and lipids. Outcome measures were obtained at 3, 6, and 12 months.

Results: The greatest reduction in weight and A1c occurred within the first three months. Weight loss occurred faster in the low-carbohydrate arm compared to the low-fat arm (p=.005), but at one year there was a similar 3.4% weight reduction in both arms. There was no significant change in A1c in either arm at one year. There was no change in blood pressure, but a greater increase in HDL was observed in the low-carbohydrate arm (p=.002).

Conclusion: Among patients with type 2 diabetes, a low-carbohydrate compared to a low-fat diet had similar effects on weight and A1c following one year. There was no significant effect on blood pressure but the low-carbohydrate diet had a greater increase in HDL cholesterol.

Type 2 Diabetes affects over 20 million people in the United States.(1) Optimal weight loss strategies in patients with type 2 diabetes continue to be debated and the best dietary strategy to achieve both weight loss and glycemic control in type 2 diabetes is unclear.

Prior studies, done primarily in patients without diabetes, demonstrate comparable weight loss outcomes with low-carbohydrate diets compared to other diets.(2-6) Based on the effectiveness of low-carbohydrate diets for weight loss, recent guidelines from the American Diabetes Association state that for short term weight loss either a low-carbohydrate or low-fat calorie restricted diet may be effective.(7)

In addition to weight loss, the metabolic effects of low-carbohydrate diets may be of particular benefit in type 2 diabetes. Carbohydrates are the primary source of glucose for metabolism and restricting carbohydrate intake can reduce insulin levels, reduce postprandial hyperglycemia, and improve insulin sensitivity. (8) (9)In short-term randomized studies, and long-term observational studies, low-carbohydrate diets have shown benefits for improving glycemic control in type 2 diabetes. (9-12)

To date, studies examining low-carbohydrate diets specifically in patients with type 2 diabetes have had small sample sizes, lacked control groups, or had short follow-up. (13) We conducted a non-blinded, two-arm randomized clinical trial to compare the effects of a one year intervention of a low-carbohydrate diet to a low-fat diet on weight and glycemic control in overweight patients with type 2 diabetes. We hypothesized that a low-carbohydrate diet compared to a low-fat diet would result in greater improvement in weight and glycemic control.

METHODS

Participants: Eligible participants were adults age>18 years with a diagnosis of type 2 diabetes for at least 6 months; body mass index (BMI) $\geq$25; and Hemoglobin A1c (A1c) between 6-11%. Exclusion criteria were a weight change of >10 lbs within 3 months of screening, kidney disease (defined as creatinine >1.3mg/dL), active liver or gall bladder disease, significant heart disease, history of severe (requiring hospitalization) hypoglycemia, or use of weight loss medications. Participants were recruited from the offices of primary care physicians, endocrinologists, and from the local community in the Bronx, NY through physician referral, letters of invitation, and posted advertisements. All study visits occurred at the Clinical Research Center of Albert Einstein College of Medicine. The study was approved by the Internal Review Boards of Albert Einstein College of Medicine and Montefiore Medical Center. All participants provided written informed consent.

Screening & Enrollment: Study enrollment was completed between August 2004 and November 2006. As seen in Figure1; 334 responded to the recruitment effort and 154, who were eligible, entered a 3-4 week pre-randomization protocol. During pre-randomization, participants were taught and asked to complete dietary and blood glucose self-monitoring activities. Participants received self-monitoring supplies that included measuring cups, food scales, and blood glucose meters with test strips (Ascensia Elite XL). Forty-nine participants discontinued during pre-randomization leaving 105 participants who were randomized.

Dietary Interventions: Using a computer-generated 1:1 randomization, participants were assigned to either a low-carbohydrate or a low-fat diet. The low-carbohydrate diet was modeled after the Atkins diet (14) and was initiated with a 2 week phase of carbohydrate restriction of 20-25 grams daily depending on baseline weight. As participants achieved weight loss, they were able to increase carbohydrate intake at 5 gram increments each week. The low-fat diet was modeled after the Diabetes Prevention Program.(15) Participants received a fat gram goal, which was 25% of energy needs, based on baseline weight. Participants in each arm received a booklet with the carbohydrate or fat content of common foods and instructions for self-monitoring. Participants were responsible for their own food purchases and food preparation. We provided participants with general recommendations to achieve 150 minutes of physical activity each week, but this was not an emphasis of the study.

Nutrition Counseling: At randomization, all participants received 45 minutes of individual dietary instruction by a registered dietitian and were given a specific gram allowance of carbohydrates or fat to achieve a 1 pound weight loss each week. Structured menus which provided meal choices and recipes were used for the first 2 weeks. (16) After the first 2 weeks, participants were instructed on selecting food choices, without using the menus, which met their dietary goals. During the 12 month study, participants had a total of 6 scheduled, 30-minute visits with the dietitian for additional dietary counseling.

Medication Adjustments: During pre-randomization, we adjusted diabetes medications to minimize side effects that could affect study findings e.g. discontinuing thiazolenediones (due to weight gain as a side effect)(17) and changing short acting insulin to insulin glargine to minimize risk of hypoglycemia.(18) At randomization and during the remainder of the study, we used a pre-defined algorithm for medication adjustments. The algorithm was developed by study investigators based on clinical experience and prior diabetes studies (19,20) and reviewed by a clinical panel of experts which included diabetologists, dietitians, primary care providers, and a certified diabetes educator. At randomization, the algorithm included reducing insulin dosages by 50% and discontinuing sulfonylurea in the low-carbohydrate arm, and reducing insulin by 25% and decreasing the sulfonylurea dose by 50% in the low-fat arm. Subsequently, the algorithm for medication adjustment was the same in both groups. Adjustments of insulin and sulfonylurea were made based on results of self-monitored capillary blood glucose. Metformin was not adjusted during the study.

Study Visits: For the first month after randomization, participants had individual study visits once or twice weekly, and following the first month, participants had scheduled visits every 6 weeks. During these visits, weight and blood pressure was measured, and participants received counseling from the study staff (study physician and research assistant) which focused on diabetes management, adjustment of diabetes medications, and dietary adherence. Ascertainment of study outcomes was done during the scheduled study visits closest to the 3, 6, and 12 month time-point following randomization.

Outcomes: Primary outcomes were weight and glycemic control (measured by A1c) We additionally collected data on blood pressure (measured with a manual sphygmomanometer following a 5 minute rest period), lipids (measured from serum samples collected after an overnight fast). Weight was measured with participants in light clothing and bared feet, using a digital scale (Tanita Brand BF 681). Measurements for A1c, total cholesterol, HDL cholesterol, and triglycerides, were carried out by enzymatic immunoassay (Olympus AU400 chemistry auto analyzer). LDL levels were calculated using the Friedewald equation. (21) All laboratory analyses were done in the Clinical Research Center.

Dietary Intake: At baseline, 6, and 12 months we collected single-day 24-hour recall by in person interviews. Participants were also instructed to keep daily food diaries which were reviewed during the study visits. Because 24-hour recall was not collected as a part of the study protocol at 3 months, we obtained dietary data for 3 months by analyzing participant food diaries for one day prior to their 3 month appointment. Nutrient data was analyzed using FoodWorks Version 8.01.

Statistical Analysis: Means and standard deviations described the distribution of baseline variables. Primary outcomes were 12 month change in weight and A1c. Hierarchical linear models analyzed all available data. We fitted a linear spline model dividing study time into two phases- an early phase months 0-3, and a late phase months 3-12. Person-level random slopes during both phases and intercepts at the person level were included. Treatment group was represented by an indicator variable, and coefficients of treatment X time interaction terms were used for inference about dietary differences. To control for medication changes, we included the change in insulin, and change in sulfonylurea at each time point as a covariate in the model with age, sex, and race. Medication changes were not significantly associated with weight and were dropped from the weight model. The analyses were done with and without imputation of missing values.

Repeated measures ANOVA with diet as the between subject factor and time as the within subject factor compared mean changes of blood pressure and lipids. Unpaired t-tests or Wilcoxon rank tests compared dietary compostion at each time point. For these analyses, we included only data for which there were results for all time points.

With a sample size of 105 participants, we had 80% power to detect a mean (±SD) difference in weight of 4.3 (±7.2) pounds and in A1c of 0.7 (±1.3) % between dietary arms. All statistical tests were 2-tailed with significance level of 0.05. Analyses were done with SPSS 15.0, and STATA 10.1.

RESULTS

At baseline, participants were similar in demographics, glycemic control, diabetes medications, blood pressure, and lipids. (See Table 1) Only 13% reported current tobacco use and this did not differ between dietary arms. Baseline differences in weight between the dietary arms were adjusted for in the statistical model.

Attrition: Data collection of weight and A1c was complete for 91% of participants at 3 months (n=95), 80% of participants at 6 months (n=84), and 81% of participants at 12 months (n=85).

There was no difference in attrition between dietary arms.

Weight: Weight change at each time point is shown in Table 2. After adjusting for age and sex, baseline differences in weight were not significant (p=0.149). During the first 3 months, the low-carbohydrate arm lost an average of 3.8 pounds per month (95% CI 3.1 to 4.5) and in months 3-12 gained an average of 0.5 pounds per month (95% CI 0.20 to 0.76). The low-fat arm in contrast lost weight at a slower rate of 2.7 pounds per month (95%CI 1.9 to 3.4) and plateaued during months 3-12 with an average weight gain of .01 lbs per month (95% CI -0.28 to 0.30). At one year, there was a 3.4% weight reduction in both arms. The difference in the early and late phase rates of weight change between the dietary groups was significant. (p=.005) In a sensitivity analysis that carried forward the baseline weight for missing values, the findings were similar.

Glycemic Control: Change in A1c at each time is seen in Table 2. There was no difference in the rate of change in A1c in either the early or late phase of dietary intervention. On average, participants experienced a decrease in A1c of 0.12 per month during the early phase, (months 0-3) but an increase of 0.06 per month during the late phase (months 3-12). Participants with higher baseline A1c levels had more rapid declines in A1c during the first 3 months (r=-0.35, 95% CI -0.11 to -0.55), but baseline levels did not affect the rate of change in A1c in months 3-12. There was an association between medication changes and A1c such that increases in insulin dose or sulfonylurea dose were associated with slightly higher A1c levels. Of the participants on insulin, the dose was reduced by a mean (±SD) of 10±14 units in the low-carbohydrate arm and increased by 4 ±19 units in the low-fat arm (p=0.12) at 12 months. Twenty-six percent of participants prescribed sulfonylurea had a reduction in sulfonylurea dose at 12 months. The mean (±SD) change in sulfonylurea dose was a 1.6±3.6 mg reduction in both arms. Imputation of baseline measurements for missing A1c values yielded similar results.

Blood Pressure: Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were similar between arms at baseline and did not change over the 12 month period. (Table 2)

Lipids: Over 12 months, there were no significant differences in total cholesterol, triglycerides or calculated LDL between dietary arms. There was a significant increase in HDL in the low carbohydrate arm which occurred at 6 months and was sustained at 12 months. (Table 2)

Dietary Adherence: At baseline, dietary arms did not differ with respect to calorie or macronutrient intake; approximately 43% of calories were from carbohydrates, 36% from fat, and 23% from fats. Based on food records, at 3 months participants in the low-carbohydrate arm had an intake of 24% of calories from carbohydrate (equivalent to 77±44 grams of carbohydrates daily), and 49% of calories from fat. The low-fat arm had an intake of 53% of calories from carbohydrate (equivalent to 199± 69 grams of carbohydrates), and an intake of 25% of calories from fat. As seen in Table 3, at 6 and 12 months, there was an increase in calories and macronutrients in both arms suggesting decreased adherence.

DISCUSSION

Our results indicate that after one year, overweight patients with type 2 diabetes had similar weight reduction with both a low-carbohydrate and a low-fat diet. Similar to prior studies we observed a more rapid weight loss after initiating a low-carbohydrate diet and equivalent weight loss following one year. (2,3) Despite modest weight reduction in both arms, there was no significant reduction in A1c. Participants in the low-carbohydrate arm achieved an initial mean reduction of A1c 0.6% in the first 3 months, but this was not sustained. Prior studies demonstrated that a 6 kg weight loss was associated with A1c reduction of .55%.(22) Study participants achieved a 3 kg weight loss which may not have been sufficient to impact A1c. The lack of change in A1c should also be taken in the context of reduced medications. One-third of all participants were on thiazolenedione medications prior to randomization which were discontinued during pre-randomization and were not restarted. Additionally, there was an overall reduction in insulin and sulfonylurea dose. Perhaps we would have observed greater reductions in A1c if we did not make medication adjustments during the study, however due to concerns of hypoglycemia, this would not have been appropriate.

The initial difference in weight loss between arms was similar to that observed previously.(2,3) While there is debate regarding the effects of macronutrient composition on weight loss, it would appear from our results that participants in the low-carbohydrate arm reduced their caloric intake to a greater extent than participants in the low-fat arm. Additionally, low-carbohydrate arm participants had greater reduction in insulin dose and due to insulin's potential effect on weight gain this reduction may have promoted a greater weight loss.

Dietary adherence is a key factor in achieving weight loss with any diet. (5) Our diverse patient population, 80% of whom were Black or Hispanic had high carbohydrate and fat intake at baseline. Culturally, Hispanic diets may have higher amounts of carbohydrate intake than the general U.S. population (23) and following a low-carbohydrate diet may have posed an even greater challenge for this population.

We did not observe any change in blood pressure at one year but did observe an increase in HDL in the low-carbohydrate arm, which is consistent with prior studies. (2,24) Participants in the low-carbohydrate arm increased their total and monounsaturated fat intake which may have contributed to this increase. In contrast to previous studies, we did not observe significant reductions in triglycerides which may be due to low triglyceride levels at baseline.

We did not have outcomes of A1c and weight for 19% of participants at 12 months. This attrition rate is lower than found in many dietary interventions. (13) We analyzed the data carrying forward baseline values for these missing outcomes, assuming that any weight lost during the study was regained. This analysis did not change our results. However if participants withdrew because they gained weight beyond their baseline weight, then our weight results would be less favorable.

Several limitations should be considered in interpreting our findings. Despite randomization, participants in the low-fat arm were heavier at baseline than the low-carbohydrate arm. While we controlled for this imbalance statistically, it raises the question of whether there were other unmeasured differences between the arms. We used single day dietary recall or single day food record to assess dietary intake, which is subject to bias. Participants may not have fully recalled their dietary intake and in addition may have changed their dietary intake for the day prior to their scheduled appointment. We did not have objective measures of physical activity, which could be a confounder, however given the similarity of our findings in both groups at one year it is unlikely that there were significant changes in physical activity in either group

In conclusion, our study demonstrates that among overweight patients with type 2 diabetes, there was no significant difference in the weight or A1c change in participants following a low-carbohydrate compared to a low-fat diet for 12 months. Participants achieved an average of a 3.4% weight reduction in both arms, but did not reduce A1c. Differences in the short-term effects of each diet were not sustained.

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Table 1. Baseline Participant Characteristics*

	Low-Carbohydrate N=55	Low-fat N=50
Age, years	54 (6)	53 (7)
Female sex, No. (%)	45 (82)	37 (74)
Race, No. (%)		
Black	34 (62)	33 (66)
Hispanic	8 (15)	9 (18)
White	8 (15)	7 (14)
Asian	2 (4)	1 (2)
Other	2 (4)	0
Physical Measures		
Weight (kg)	93.6 (18)	101 (19)
Body Mass Index (kg/m2)	35 (6)	37 (6)
Systolic Blood Pressure	125 (18)	130 (17)
Diastolic Blood Pressure	73 (9)	77 (10)
Clinical		
HbA1c (%)	7.5 (1.5)	7.4 (1.4)
Total Cholesterol (mmol/L)	4.4 (.83)	4.3 (.86)
Low Density Lipoprotein (mmol/L)	2.5 (.69)	2.4 (.74)
High Density Lipoprotein (mmol/L)	1.3 (.24)	1.2 (.29)
Triglycerides (mmol/L)	1.4 (.84)	1.4 (.67)
Medications, No (%)		
Metformin	43 (78)	43 (86)
Sulfonylurea	24 (44)	26 (52)
Insulin	19 (35)	12 (24)
Cholesterol Lowering Medication	34 (62)	28 (56)

* Values are expressed as mean (SD) unless otherwise noted.

Table 2. Change in Anthropometric and Metabolic Outcomes at 3, 6, and 12 months after diet initiation.

Variable	3 months	6 months	12 months	p-value
HbA1c*				
Low-carbohydrate diet	-.64 (1.4)	-.29 (.92)	-.02 (.89)	.71
Low-fat diet	-.26 (1.1)	-.15 (1.1)	.24 (1.4)	
Weight* (kg)				
Low-carbohydrate diet	-5.2 (2.8)	-4.8 (3.5)	-3.1 (4.8)	.005
Low-fat diet	-3.2 (3.7)	-4.4 (5.3)	-3.1 (5.8)	
Systolic BP (mmHg)				
Low-carbohydrate diet	-5.8 (19.2)	-.78 (17.7)	2.0 (15.6)	.15
Low-fat diet	-.98 (21.0)	-37 (19.8)	-1.8 (22.6)	
Diastolic BP (mmHg)				
Low-carbohydrate diet	-2.2 (12.5)	-.93 (12.4)	-2.9 (9.4)	.62
Low-fat diet	-.40 (12.6)	.95 (9.8)	-2.2 (11.6)	
Total Cholesterol mmol/L †				
Low-carbohydrate diet		.05 (.79)	.10 (.76)	.37
Low-fat diet		-.27 (.74)	-.13 (.70)	
Low Density Lipoprotein mmol/L				
Low-carbohydrate diet		-.10 (.52)	-.04 (.63)	.23
Low-fat diet		-.25 (.56)	-.18 (.66)	
High Density Lipoprotein mmol/L				
Low-carbohydrate diet		.16 (.28)	.16 (.27)	.002
Low-fat diet		-.01 (.22)	.06 (.21)	
Triglycerides mmol/L				
Low-carbohydrate diet		-.02 (.85)	-.15 (.88)	.53
Low-fat diet		.04 (.56)	-.01 (.86)	

* represent p-values for diet difference over all time points.
† lipid values were not collected at 3 months

Table 3. Dietary Intake at Each Time Point

Variable	**Baseline**	**6 months***	**12 months†**
Caloric Intake (kcal/day)			
Low-carbohydrate diet	1983 (650)	1652 (650)	1642 (600)
Low-fat diet	1863 (450)	1653 (471)	1810 (590)
p-value for low-carbohydrate vs. low-fat	*.28*	*.99*	*.30*
Carbohydrate Intake (%total energy)			
Low-carbohydrate diet	43.9 (9.1)	33.5 (14.7)	33.4 (13.2)
Low-fat diet	41.2 (10.4)	48.1 (14.1)	50.1 (10.0)
p-value for low-carbohydrate vs. low-fat	.14	<.001	<.001
Fat Intake (%total energy)			
Low-carbohydrate diet	36.1 (7.6)	43.0 (13.1)	**43.9 (10.8)**
Low-fat diet	38.8 (9.4)	30.8 (9.8)	30.8 (10.2)
p-value for low-carbohydrate vs. low-fat	.12	<.001	<.001
Saturated Fat† (% total fat)			
Low-carbohydrate diet	31.3 (7.9)	28.6 (8.8)	28.7 (9.6)
Low-fat diet	31.5 (7.0)	30.7 (8.4)	30.2 (5.4)
p-value for low-carbohydrate vs. low-fat	.91	.33	.43
Polyunsaturated Fat† **(% total fat)**			
Low-carbohydrate diet	19.1 (7.6)	19.1 (7.5)	17.4 (8.0)
Low-fat diet	19.6 (9.0)	19.8 (8.0)	21.4 (8.6)
p-value for low-carbohydrate vs. low-fat	.76	.70	.06
Monounsaturated Fat† **(% total fat)**			
Low-carbohydrate diet	36.1 (7.0)	39.5 (11.0)	40.7 (10.4)
Low-fat diet	37.6 (6.9)	35.2 (8.7)	38.1 (6.9)
p-value for low-carbohydrate vs. low-fat	.28	.08	.25
Protein Intake (%total energy)			
Low-carbohydrate diet	19.5 (6.3)	22.5 (6.0)	22.7 (6.7)
Low-fat diet	19.4 (6.6)	20.5 (7.0)	18.9 (4.7)
p-value for low-carbohydrate vs. low-fat	.94	.18	.02
Fiber (grams/day)			
Low-carbohydrate diet	15.4 (8.5)	12.6 (10.7)	15.1 (9.5)
Low-fat diet	14.9 (8.5)	17.0 (9.7)	17.2 (8.1)
p-value for low-carbohydrate vs. low-fat	.78	.09	.36

* based on 24 hour recall from 68 participants † based on 24 hour recall from 57 participants

Figure 1 Participant Flow