

The impact of low-carbohydrate diet on glycemic control in Native Americans

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Abstract: Many studies have shown that a low-carbohydrate diet (LCD) is a safe and effective intervention to improve glycemic control. However, published data are limited regarding the use of carbohydrate restriction in the treatment and prevention of type 2 diabetes mellitus (DM) in the Native Americans, in a real-world clinical practice setting. We evaluated the efficacy of an LCD on 50 obese Native Americans with either type 2 DM or impaired fasting blood glucose (IFG) in a primary care/obesity medicine practice. The primary intervention was an LCD defined as an intake of <20 g of carbohydrates per day. The intervention involved providing an educational handout and behavioral counseling assisted by a dedicated weight loss coordinator. We evaluated the effects of this intervention on hemoglobin A_{1c}, body weight, blood pressure, and lipid parameters. The subjects were evaluated at baseline and 6 months. The subjects underwent additional safety and counseling visits throughout the study. Subjects were considered completers if they had baseline and 6-month measurements. The mean age was 55.0±10.9 years, and 66.7% were female. Subjects had significant improvements in hemoglobin A_{1c} (−1.4%±0.9%, in subjects with DM, $P<0.0001$), fasting blood glucose (−15±4.9 mg/dL, in subjects with IFG, $P<0.0001$), and body mass index (−4.0±1.7 kg/m², $P<0.0001$). An LCD can lead to clinically and statistically significant improvement in glycemic control and body weight among obese subjects with type 2 DM or IFG over a 6-month period. The results suggest that carbohydrate restriction can be an effective real-world intervention in a primarily Native American clinical practice. However, further studies are needed to assess long-term compliance and potential weight regain.

Keywords: diabetes mellitus, impaired fasting glucose, diet

Introduction

Native Americans show the highest rate of diabetes mellitus (DM) in the world, according to a study published by the National Institutes of Health, making it a major public health problem in these communities.¹ Several theories have been suggested, attributing to the higher prevalence of DM in this ethnic group including their particular lifestyle, diet, and social conditions along with underlying genetic susceptibility. Lumbee Indians are the largest Native American community in North Carolina (NC), named after the Lumbee River. The majority of Lumbee Indians live in Robeson County, one of the poorest rural counties, located in the coastal plains of southeastern NC.² Native Americans, in general, have lower economic, educational, and health care access, with nearly one in three living below the poverty level. This population group in NC is three times more likely to die from DM and 30% more likely to die from cardiovascular complications related to DM than non-Hispanic Whites in this state.³ In 2009, the age-adjusted diabetes death rate among residents of Robeson County was 57.4 deaths per

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100,000 population, more than double the rate for the state of NC.⁴ Furthermore, diabetes in this population is seen at an earlier age of 35–40 years, leading to serious long-term premature vascular complications. In 2008, Lumbee Indians also had the highest obesity rate in NC (43.1% as compared to the state at 29.5%).¹

Despite continuous efforts, there has been a global failure to halt the epidemic of diabetes worldwide under current guidelines.⁵ The use of low-carbohydrate diets (LCDs) has been studied previously as a potential strategy to control DM. Many studies to date have demonstrated that lowering the percentage of dietary carbohydrate can improve glycemic control among individuals with type 2 DM and halt the progression of prediabetes to full-blown DM.^{6–10} Additionally, some randomized studies on LCD have also shown a significant benefit on weight loss for the treatment of obesity.¹¹ However, there are limited data available regarding the management and prevention of DM in the Native American population, specifically regarding the impact of a dietary intervention. As the efficacy of any intervention can differ from one ethnic group to the other, due to various factors such as genetic predisposition, lifestyle, cultural beliefs, and other variables particular to that population, we designed a study to address this issue.

In this study, we aimed to determine the impact of an LCD on type 2 DM in the largest Native American obese population in NC, in a real-world clinical practice setting.

Materials and methods

Participants

This pilot study was conducted at Southeastern Lumberton Clinic in Lumberton, NC. Fifty Native Americans, who were obese, interested in losing weight, and had either type 2 DM or impaired fasting blood glucose (IFG or prediabetes), were enrolled in the weight loss program at our primary care clinic for at least 6 months after attaining informed written consent. A medical history was taken, physical examination performed, and basic laboratory tests were drawn. The inclusion criteria were type 2 DM (confirmed by hemoglobin A_{1c} [HbA_{1c} >6.5%]) or IFG (confirmed by 100 mg/dL < fasting blood glucose [FBG] <125 mg/dL) for >1 year, onset of DM or IFG after 18 years of age, no history of diabetic ketoacidosis, age 18–65 years, body mass index (BMI) from 30 kg/m² to 50 kg/m², and desire to lose weight. Exclusion criteria were the following: unstable or any serious medical conditions; significant comorbid illnesses such as liver disease, kidney disease, congestive heart failure, and cancer; pregnancy; or nursing. No monetary incentives

were given. All aspects of this study were approved by the Southeastern Regional Medical Center Institutional Review Board, and adhered to the guidelines of the Declaration of Helsinki.

Interventions

The primary intervention included providing all participants 1) a dietary handout, 2) recommendations to engage in some form of physical activity for 30 minutes for at least three times per week, and 3) maintaining a weekly food and activity diary. The program also involved providing educational material regarding diabetes, obesity, lifestyle changes, and nutritional counseling assisted by a dedicated weight loss coordinator. Participants on antidiabetic medication had their medications reviewed; the dosages of insulin and/or oral hypoglycemic were adjusted or discontinued accordingly by the physician.

The dietary recommendation consisted of a diet with restricted intake of dietary carbohydrate to less than or equal to 20 g per day, without specifically decreasing the calorie intake. Allowed foods on the diet were unlimited amounts of animal foods (ie, meat such as chicken, turkey, fish, shellfish) and eggs, and limited amounts of hard cheese (eg, cheddar or Swiss, 4 ounces per day), fresh cheese (eg, cottage or ricotta, 2 ounces per day), salad vegetables (two cupfuls per day), and non-starchy vegetables (one cupful per day). Participants were encouraged to drink at least six glasses of water per day.

The participants were followed up closely with the same physician and a dedicated weight loss coordinator initially weekly for 2 weeks, then biweekly for 1 month, and then monthly for the remaining 4 months and earlier if needed to ensure dietary adherence. In addition, participants were advised to closely monitor their blood sugars by logs, which were reviewed along with food and activity diaries to ensure safety and compliance of the subjects. Weight and blood pressure (BP) were measured in each visit. Body weight was measured in light indoor clothes without shoes to the nearest 0.1 pound, using a high-quality calibrated digital scale. Height was measured using a wall-mounted stadiometer and recorded to the nearest 0.1 cm. BMI was calculated from these measurements as (body weight in kilograms)/(height in meters)². BP was obtained from the right arm with an appropriate-sized cuff and an oscillometric BP machine after the participant was seated quietly for 5 minutes. We obtained a total of three BP measurements with 30 seconds rest in between; the average of the readings was calculated, and the value used for data analysis.

Table 1 Demographic data

	Diabetics	Prediabetics	Total
Number of patients	38	12	50
Age (years)*	54.9±9.1	55.3±15.4	55.0±10.9
Sex (female) (%)	60	85.7	66.7

Note: *Data are presented as mean ± SD.

Measurements were performed by trained nurses in a real-world clinical setting.

The impact of this intervention on HbA_{1c}, FBG, BMI, BP, and lipid parameters was evaluated at baseline and 6 months. Subjects were considered completers if they had baseline and 6-month measurements. Similarly, in subjects with IFG, FBG was also measured at baseline and 6 months. Blood tests were obtained in the morning after at least 8 hours of fasting and processed by a commercial laboratory. The main outcome of the study was to evaluate glycemic control from baseline to 6 months. Secondary outcomes were changes in BMI, BP, and lipid parameters.

Statistical analysis

Comparisons between values before and after intervention were performed using the paired *t*-test. For all analyses, a *P*-value of <0.05 was considered statistically significant. Analyses were performed using JMP Statistical Software, Version 11 (SAS Institute Inc., Chicago, IL, USA).

Results

Fifty obese subjects were enrolled. The mean age was 55.0±10.9 years, and 66.7% were female. Table 1 shows the demographic characteristics of these participants. For further evaluation of glycemic control, these subjects were divided into two subgroups based on their diabetes status.

Participants had a mean baseline BMI of 39.7±8.2 kg/m² and a mean weight of 111.7±21.2 kg before the intervention. After 6 months of follow-up, subjects lost an average

weight of 11.1±4.4 kg (10.0%±3.7% total weight loss and 32.0%±16.1% excess weight loss, *P*<0.0001). The mean BMI decreased by 4.0±1.7 after intervention (*P*<0.0001). Additionally, participants had significant improvements in systolic (−17.2±8.9 mmHg, *P*<0.0001) and diastolic BP (−10.32±8.3 mmHg, *P*<0.0001). Subjects had significant improvement in total (−22.1±24.0 mg/dL, *P*<0.0001), low-density lipoprotein (LDL) (−46.3±22.2 mg/dL, *P*<0.0001), high-density lipoprotein (HDL) cholesterol (+2.8±7.2 mg/dL, *P*<0.0135), and also triglycerides (TG) (−46.3±22.2 mg/dL, *P*<0.0001) (Table 2).

In subjects with DM, HbA_{1c} decreased by 1.4%±0.9%, and a mean HbA_{1c} of 6.5%±0.6% was achieved. Most participants had reduction or elimination of antidiabetic medications. In subjects treated with insulin, the total required insulin dose was significantly decreased (−36±34 U/day, *N*=15 [30%], *P*=0.0017], and one subject discontinued insulin entirely. The dose of metformin was also significantly reduced (−421±576 mg, *P*=0.0005) (Table 3).

In prediabetic subjects, the mean FBG decreased by 15±4.9 mg/dL, reaching the mean of 90.6±4.2 mg/dL (*P*<0.0001) (Table 4).

Discussion

Despite all advances in medical therapy, the epidemic of diabetes in Native Americans remains uncontrolled, which makes reevaluation of dietary intervention essential. LCDs have been described to be beneficial in subjects with DM in many studies.¹² An LCD helps control hyperglycemia by decreasing the glycemic content and also the patient's weight, which has been shown to improve DM independently.^{13,14} Since hyperglycemia is the major feature of DM and IFG, reducing the carbohydrate intake effectively and immediately lowers the blood glucose levels.¹²

Achieving better glycemic control requires a multi-aspect approach including lifestyle modification, dietary

Table 2 Disease characteristics before and after intervention

	Baseline	After intervention	Change	<i>P</i> -value
Weight (kg) (N=50)	111.7±21.2	100.0±19.8	−11.1±4.4	<0.0001
Body mass index (kg/m ²) (N=50)	39.7±8.2	35.4±7.1	−4.0±1.7	<0.0001
SBP (mmHg) (N=50)	135.9±9.6	118.5±7.5	−17.2±8.9	<0.0001
DBP (mmHg) (N=50)	80±7.5	69.7±5.2	−10.32±8.3	<0.0001
Total cholesterol (mg/dL) (N=43)	180.3±34.2	157.2±28.7	−22.1±24.0	<0.0001
LDL (mg/dL) (N=43)	106.6±29.3	87.5±23.8	−46.3±22.2	<0.0001
HDL (mg/dL) (N=43)	41.2±8.3	44.4±9.7	+2.8±7.2	0.0135
TG (mg/dL) (N=43)	164.7±42.1	122.1±33.3	43.8±47.8	<0.0001

Note: All measures are presented as mean ± SD.

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure; LDL, low-density lipoprotein; HDL, high-density lipoprotein; TG, triglyceride.

Table 3 Variables before and after intervention in patients with DM

	Baseline	After intervention	Change	P-value
HbA _{1c} (%)	8.0±1.0	6.5±0.6	-1.4±0.9	<0.0001
Number of oral hypoglycemic agents	1.3±0.6	1±0.4	-0.3±0.5	0.0008
Metformin dose (mg)	1,959±183	1,483±650	-421±576	0.0005
Total insulin dose (U)	54.4±46.8	17±19.5	-35.6±33.9	0.0017
Statin dose (mg)	36.9±16.6	33.6±13.2	-3.0±10.1	0.096
Number of antihypertensive agents	1.10±0.37	1.07±0.36	-0.02±0.16	0.32

Note: All measures are presented as mean ± SD.

Abbreviations: HbA_{1c}, hemoglobin A_{1c}; DM, diabetes mellitus.

intervention, and pharmaceutical therapy; in all of these, subjects' compliance plays an important role. Compliance is determined by several factors such as personal beliefs and patient–physician interaction. Glycemic control in Lumbee Indians has been described to be difficult due to lower economic, educational, and health care access.² However, this study reflects an effective intervention, as almost all subjects were able to comply with the given diet by completing the 6 months of follow-up, with an improvement in glycemic control and diabetic medication elimination/reduction.

One should consider that the immediate reduction in glucose levels poses a danger of hypoglycemia in subjects on hypoglycemic agents such as sulfonylurea and insulin. Therefore, it is recommended that the physician reduces both the dosage of insulin and hypoglycemic medication accordingly with the initiation of the diet. Subjects should be counseled to closely monitor their blood glucose levels and follow up with their physician to adjust the medications. It is advised that subjects should avoid LCD without any close medical supervision.

Weight loss has been shown to be beneficial in the management and prevention of type 2 DM. Apart from its beneficial impact on glycemic control, LCD is also one of the most effective dietary interventions for weight loss.¹² The advantage of LCD is that subjects achieve satiety faster with the high-fat/high-protein diet without actually restricting their calorie intake. The carbohydrate is mostly replaced by either fat or protein. However, a high-protein diet is discouraged in subjects with impaired renal function. Both protein and fat

tend to be stable self-limiting part of the diet. Like previous studies, LCD in this study also led to significant weight loss, suggesting that an LCD can effectively decrease weight.

The goal of management in subjects with IFG (prediabetes) is to prevent them from developing overt DM, which can be achieved by lifestyle modification.¹⁵ Not only was this intervention a clinical trial for subjects with established DM but also a preventive trial for prediabetic subjects. Normalization of FBG was achieved at the last follow-up in all of our 12 prediabetic subjects. This suggests that an LCD can be an effective preventive tool in the management of subjects with IFG.

LCD has been shown to be one of the most effective methods to improve serum TG and HDL cholesterol apart from starvation. However, other parameters of lipid profile such as total and LDL cholesterol have been reported to be neither improved nor worsened.¹⁶ We found a slight but significant improvement in all lipid indices including LDL, HDL, and total cholesterol, as well as TG on the same or reduced dose of statins. These findings suggest that an LCD can improve lipid profile as well. Furthermore, by implementing this diet as a method of lifestyle modification, we noticed an improvement in all the parameters of metabolic syndrome including systolic and diastolic BP, which has also been demonstrated in other studies.¹⁷

Conclusion

In conclusion, the use of an LCD led to clinically and statistically significant improvement in glycemic control, body weight, lipid profile, and also BP among subjects with type 2 DM or IFG, over a 6-month period. The results suggest that carbohydrate restriction can be an effective real-world intervention in a primarily Native American clinical practice. However, further studies are needed to assess long-term compliance and efficacy of this intervention.

Limitations

Due to a lack of control group, it is difficult to comment whether the improvement in the study measurements is

Table 4 Variables before and after intervention in patients with IGT (prediabetics)

	Baseline	After intervention	Change	P-value
Waist circumference (cm) (N=12)	95.5±7.1	84.1±6.6	11.4±2.0	<0.0001
FBG (mg/dL) (N=12)	106.2±3.7	90.6±4.2	-15±4.9	<0.0001

Note: All measures are presented as mean ± SD.

Abbreviations: FBG, fasting blood glucose; IGT, impaired glucose tolerance.

related to the low glycemic index of the diet alone or other consequential outcomes such as weight loss.

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Disclosure

The authors report no conflicts of interest in this work.

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