

Applied nutritional investigation

## Low-carbohydrate and high-fat intake among adult patients with poorly controlled type 2 diabetes mellitus

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### Abstract

**Objective:** This study examined baseline dietary intake, body weight, and physiologic status in patients enrolled in a dietary intervention for type 2 diabetes mellitus (T2DM).

**Methods:** Dietary, physiologic, and demographic information were collected at baseline from 40 adult patients with poorly controlled T2DM (glycosylated hemoglobin >7%) who participated in a clinical trial at an academic medical center in Worcester, Massachusetts, USA.

**Results:** The average age at enrollment was 53.5 y (SD 8.4), average body mass index was 35.48 kg/m<sup>2</sup> (SD 7.0), and glycosylated hemoglobin was 8.3% (SD 1.2). Participants were predominantly white, married, and employed full time. Forty-eight percent were men. Seventy-eight percent had hyperlipidemia, and 68% had hypertension. Reported baseline daily average energy intake was 1778 kcal (SD 814), daily carbohydrate was 159 g (SD 71.5), and dietary fiber was 11.4 g (SD 5.2). The dietary composition was 35% carbohydrate, 45% fat (15% saturated fat), and 20% protein. The American Diabetes Association (ADA) guidelines recommends 45–65% of energy from carbohydrate, 20–35% from fat (<7% saturated), and 20% from protein.

**Conclusion:** These patients reported a low-carbohydrate, low-fiber, high-fat (especially saturated) diet, although they stated they are not following any of the popular low-carbohydrate diets. Patients with T2DM may find the current trend toward reducing weight through low-carbohydrate diets attractive for control of blood glucose, despite ADA recommendations. This dietary pattern may represent a popular trend that extends beyond our particular study and, if so, has serious cardiovascular implications in this vulnerable population of T2DM patients. © 2006 Elsevier Inc. All rights reserved.

### Keywords:

Dietary carbohydrate; Dietary fats; Diabetes mellitus, type 2; Cardiovascular diseases; Dietary fiber

### Introduction

The prevalence of all types of diabetes in the United States has increased 33%, from 4.9% in 1990 to 6.5% in 1998 [1]. It subsequently rose to 6.9% in 1999, a 6% increase in 1 y [2]. In 2005, the prevalence of diabetes in the United States was 7% [3], 20.8 million Americans. Approx-

imately 94% of adults diagnosed with diabetes have type 2 diabetes mellitus (T2DM) [4]. For many, the disease is poorly managed [5] and fraught with complications. Despite the best efforts of clinicians, patients, and the American Diabetes Association (ADA), the incidence of T2DM and its complications continues to increase. Health care practitioners report a lack of resources to optimally manage the dietary intake of their T2DM patients [6]. In addition, many patients with T2DM find the ADA nutritional recommendations difficult to follow [7]. The goal for better blood glucose control through dietary self-care remains outstanding, as does the risk for disease complications.

Chief among these, cardiovascular disease is the leading

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cause of death in people with diabetes [8]. Control of modifiable cardiovascular risk factors including excess weight, hyperlipidemia, hypertension, and physical inactivity is therefore essential to T2DM management. Notably, the National Health and Nutrition Examination Survey (NHANES) 1999–2002 revealed an 85.2% prevalence of overweight or obesity among adults diagnosed with diabetes and a 54.8% prevalence of obesity (body mass index [BMI]  $\geq 30$  kg/m<sup>2</sup>) [9]. Obesity or overweight status in people with T2DM is associated with poor control of blood glucose levels, blood pressure, and cholesterol [10], placing these people at even higher risk for cardiovascular and microvascular diseases (e.g., retinopathy, nephropathy, and neuropathy) [11]. Therefore, dietary modifications and understanding are central to T2DM management.

Diets that provide low carbohydrate, low fiber, and high saturated fat contribute to disease complications in patients with T2DM and are not recommended [12]. Despite this, low-carbohydrate diets for weight loss have become popularized through media exposure and the marketing of several books (e.g., The Atkins Diet, The South Beach Diet) [13,14]. The “low-carb” trend is reflected in changes to the national food supply, with many products in grocery stores and restaurants currently available. Patients with T2DM and many physicians may find the current trend toward reducing weight through low-carbohydrate diets attractive for control of hyperglycemia, because carbohydrate intake has the greatest influence on blood glucose. However, the use of low-carbohydrate diets carries implications for other components of the diet, especially fat and fiber content, unless these dietary factors are also controlled. Further, the specific prevalence of the low-carbohydrate diet trend in patients with T2DM has not been documented. Thus, the objectives of the present study were to examine baseline dietary, physiologic, and demographic information from adult patients with poorly controlled T2DM in an academic medical center.

## Materials and methods

### Subjects

The University Hospital of the University of Massachusetts Memorial Medical Center primary care health information system database found 1203 patients ages 21 to 70 y with T2DM with glycosylated hemoglobin (HbA1c)  $\geq 7\%$ . Patients were recruited from this database for the Diabetic Educational Eating Plan study, in which subjects were randomized to a low glycemic index (GI) diet or the standard ADA diet (carbohydrate counting). Inclusion criteria for the study included: (1) diagnosis of T2DM documented in a patient’s medical chart; (2) HbA1c level  $\geq 7\%$  (an indication of poor control of T2DM [15]); (3) currently being treated with diet, oral hypoglycemic agents, and/or insulin; (4) age  $\geq 21$  y; (5) telephone in home or easy access to one;

(6) able to understand and participate in the study protocol; (7) ability to provide informed consent; (8) physician’s approval to participate in the study; (9) having a blood glucose machine or a prescription for one from the physician; (10) ability to speak and read English; and (11) a willingness to be randomized to one of the two study arms. Exclusion criteria were: (1) pregnancy or planning to become pregnant during the study; (2) unable or unwilling to provide informed consent; (3) plans to move out of the area within the 12-mo study period; (4) required intermittent glucocorticoid therapy within the previous 3 mo; (5) documented acute coronary event (myocardial infarction or unstable angina) within the previous 6 mo; (6) diagnosis of a medical condition that precludes adherence to study dietary recommendations (e.g., Crohn’s disease, ulcerative colitis, end-stage renal disease); (7) diagnosis of serious psychiatric illnesses (e.g., dementia, bipolar disorder, psychotic disorder, or psychiatric hospitalization or suicidality within the past 5 y); (8) patient is considered legally blind or has significant visual impairments; and (9) currently adhering to a low carbohydrate diet such as the Atkins’ Diet [13] or the South Beach Diet [14]. From an intervention perspective, this exclusion was because these diets are low in all sources of carbohydrate, and modification of the type of carbohydrate (GI) will have a limited effect on glycemic load (GL) and therefore on HbA1c.

Eleven primary care physicians were contacted and eight physicians agreed to participate. These eight physicians identified from the primary database a total of 154 of their patients as study candidates. Selected patients were sent a study participation invitation letter signed by their primary care physician and the principal investigator. In addition, nine patients learned about the study from flyers or messages through the intranet service at the medical school, and were then cleared by their primary care physicians. Of these 163 patients, 40 were eligible by telephone and HbA1c screening and were enrolled in the Diabetic Educational Eating Plan study.

The study intervention and data collection procedures were approved by the University of Massachusetts Medical School institutional review board for use of human subjects in medical research. All study participants provided informed consent before being enrolled in the study.

### Participant characteristics

Data on demographic variables were collected by a self-administered questionnaire at the enrollment visit. Objectively, height, weight, waist circumference, and hip circumference were measured at that time. Relative mass is expressed as BMI (weight in kilograms/height squared in meters).

Blood pressure measurements were taken using a Dinamap XL automated blood pressure monitor (GE Medical Systems Information Technologies, Tampa, FL, USA). Use of oral hypoglycemic agents, insulin, and lipid-lowering and

antihypertensive medications was recorded using a baseline questionnaire. Depressive symptoms were assessed using the Center for Epidemiological Studies Depression Scale [16,17]. Diabetes-specific emotional distress was assessed by the Problem Areas In Diabetes (PAID) measure [18]. Each item is scored 0 to 4 (“not a problem” to “serious problem”). The sum of the 20 items is multiplied by 1.25 to yield a final score from 0 to 100, with higher scores indicating greater emotional distress. The PAID is one of the most broadly used tools in diabetes research and has well-documented reliability, validity, and responsiveness [19].

#### *Blood sample collection, lipid, and glycosylated hemoglobin assays*

At the enrollment visit, a 12-h fasting blood sample was collected between 0700 and 1000 h. HbA1c and blood lipids (including total cholesterol, high-density lipoprotein, low-density lipoprotein, and triacylglycerols) were measured in the University of Massachusetts Medical Memorial Medical Hospital Center laboratory. All assays have met the standardization criteria of the Centers for Disease Control and Prevention/National Heart, Lung, and Blood Institute Lipid Standardization Program.

#### *Baseline assessment of diet and physical activity*

The 7-d dietary recall (7DDR), which is similar to a food frequency questionnaire, was used for dietary assessment at the enrollment visit. The 7DDR is designed to measure short-term changes in dietary intake, especially fat, in intervention trials [20]. According to our previous analyses, the 7DDR-derived nutrients agreed closely with those derived from multiple 24-h recalls, in which a high-level correlation coefficient ( $r = 0.53\text{--}0.77$ ) was found across nutrients [20]. Nutrient scores, such as total energy in kilocalories and carbohydrate intake, and percentage of energy from fat and carbohydrate were computed from the data collected from the 7DDR. GI, a measurement of carbohydrate quality, was determined from the 7DDR using published tables [21,22]; GL (GI of a food times the amount of carbohydrate eaten divided by 100) was also calculated, as has been previously reported by our group [23,24]. The 7DDR also included a brief validated physical activity assessment described elsewhere [25,26]. Briefly, the questionnaire asked, “During the last 28 days, did you participate in any physical activity or exercise such as running, calisthenics, golf, gardening or walking for exercise?” Subsequently the questionnaire asked subjects to describe all types of exercises they did during the past 4 wk. For their three most prevalent ways to exercise, it then asked participants to state the total daily exercise duration and its weekly frequency. For each exercise, weekly total time was calculated by multiplying the duration of exercise by its frequency. The sum of the weekly total time of the three exercises is the average leisure-time physical activity per week.

#### *Statistical analyses*

Mean  $\pm$  SD were used to describe continuous variables; frequency and percentage were used for categorical variables. All analyses were performed using STATA 8.0 (STATA Corp., College Station, TX, USA).

#### **Results**

Participants were predominantly white (85%) and between the ages of 33 and 76 y (mean  $\pm$  SD,  $53.5 \pm 8.4$ ). Ninety-five percent were overweight or obese, and 77.5% were obese (Table 1). The group was evenly divided between men and women and had a wide range of education levels. The average HbA1c was 8.3% (SD 1.2). From the baseline questionnaire, a large majority (77.5%) stated that they had difficulty with being overweight in the past and that they had tried to lose  $\geq 10$  lb in the past year. All participants stated that they were engaged in dietary management of their diabetes, although they specifically stated they were not currently following one of the popular low-carbohydrate diets and therefore met study criteria. Most participants were also taking medication for their T2DM. In addition to obesity, hyperlipidemia was the most common cardiovascular risk factor, diagnosed in 77.5% of participants. All but one participant were taking lipid-lowering medications. Lipid levels seen at baseline (with the exception of triacylglycerols) were well controlled with medication. Moreover, 67.5% of participants had been diagnosed with hypertension, and 15% with heart disease. The average depression score from the Center for Epidemiological Studies Depression Scale (mean  $\pm$  SD,  $10.6 \pm 11.4$ ) indicated mild depressive symptoms in most participants. The average PAID score, the measurement of psychosocial stress resulting from diabetes, was 26.31 (SD, 19.48), comparable to scores from a large U.S. sample of individuals with T2DM [27].

Baseline dietary intake is presented in Table 2. Reported daily average caloric intake was 1778 kcal (SD, 814), daily carbohydrate intake was 159 g (SD, 71.5) and dietary fiber intake was 11.4 g (SD, 5.2). The diet composition was 35% carbohydrate, 45% fat (15% saturated fat, 17% monounsaturated fat, and 9% polyunsaturated fat), and 20% protein. Average dietary GI (with white bread as the referent = 100) was 80.70 (SD, 5.42), and GL was 133.62 (SD, 61.82). Average leisure-time physical activity was 146.85 min/wk (SD, 122.71).

Tables 3 and 4 list the numbers and types of medications used in this study group. Of note, the most common oral medication was metformin, which was often combined with a sulfonylurea. Thiazolidinediones were always used in combination with other hypoglycemic agents and never as monotherapy. Ten people used insulin in addition to oral hypoglycemic agents. Of those using insulin, four used both short-acting and long-acting insulin, and one used an insulin

Table 1  
Baseline characteristics of participants in the Diabetic Educational  
Eating Plan study, Worcester, Massachusetts, 2005–2006

	Count (%)	Mean $\pm$ SD
Demographic information		
Age (y)		53.5 $\pm$ 8.4
Gender		
Male	19 (47.5%)	
Female	21 (52.5%)	
Education		
Less than high school	6 (15.0%)	
High school diploma	3 (7.5%)	
Some college/associate's degree	10 (25.0%)	
Bachelor's degree	14 (35.0%)	
Graduate or professional degree	7 (17.5%)	
Ethnicity		
White	34 (85.0%)	
Black	2 (5.0%)	
Asian	2 (5.0%)	
Other	2 (5.0%)	
Marital status		
Single	4 (10.0%)	
Married or living with partner	28 (70.0%)	
Separated/divorced/widowed	8 (20%)	
Work status		
Full time	22 (55.0%)	
Part time	7 (17.5%)	
Disabled (unable to work)	2 (5.0%)	
Retired	5 (12.2%)	
Volunteer	1 (2.5%)	
Unemployed	3 (7.5%)	
Health information		
Body mass index (kg/m <sup>2</sup> )		35.8 $\pm$ 7.0
Normal (<25)	2 (5%)	
Overweight (25–30)	7 (17.5%)	
Obese ( $\geq$ 30)	31 (77.5%)	
Problems with overweight	31 (77.5%)	
Tried to lose $\geq$ 10 lb in previous year	31 (77.5%)	
Smoking status		
Current smoker	4 (10.0%)	
Former smoker; no longer smokes	12 (30.0%)	
Never smoked	17 (42.5%)	
Diabetes treatment		
Diet only	4 (10%)	
Diet and medication	36 (90%)	
Exercise	12 (30%)	
Diabetes medications used		
Oral hypoglycemics only	22 (55%)	
Insulin only	4 (10%)	
Combination of oral hypoglycemic and insulin	10 (25%)	
Diabetes complications		
None	13 (32.5%)	
Heart disease	6 (15%)	
Hypertension	21 (52.5%)	
Nephropathy	2 (5.0%)	
Eye problems	5 (12.5%)	
Neuropathy	3 (7.5%)	
Infections	1 (2.5%)	
Other	1 (2.5%)	
Glycosylated hemoglobin		8.3 $\pm$ 1.2
Lipids		
Diagnosed with high cholesterol	31 (77.5%)	

Table 1  
Continued

	Count (%)	Mean $\pm$ SD
Taking lipid-lowering medications	30 (75%)	
Total cholesterol (mg/dl)		171.7 $\pm$ 37.1
Low-density lipoprotein (mg/dl)		91.0 $\pm$ 34.6
High-density lipoprotein (mg/dl)		44.1 $\pm$ 10.3
Triacylglycerols		185.2 $\pm$ 121.8
Blood pressure		
Diagnosed with hypertension	27 (67.5%)	
Taking antihypertensive medications	24 (60%)	
Systolic blood pressure (mmHg)		131.2 $\pm$ 12.2
Diastolic blood pressure (mmHg)		78.2 $\pm$ 7.6
Psychosocial factors		
CES-DS score		10.6 $\pm$ 1.4
PAID score		26.31 $\pm$ 19.48

CES-DS, Center for Epidemiological Studies Depression Scale; PAID, Problem Areas In Diabetes

pump. One person used the injectable incretin mimetic, exenatide, in addition to two oral agents and neutral protamine hagedorn (NPH) insulin.

## Discussion

Low-carbohydrate and high-fat intakes were observed at baseline among most participants with poorly controlled T2DM at our primary care clinic, despite the exclusion of patients following low-carbohydrate dietary programs such as the Atkins and South Beach diets. The lower-carbohydrate intake appeared to reflect the usual dietary pattern for these patients and was associated with a high saturated fat intake and a low dietary fiber intake. Our observations may be representative of many other patients with T2DM, and perhaps of a trend in the wake of the low-carbohydrate diets. Such a diet likely has cardiovascular implications for patients with T2DM, obesity, hypertension, and hyperlipidemia. Although many researchers are advocating this low-carbohydrate approach to diabetic management [28,29], more research is needed to determine the effect of this dietary recommendation on other macronutrients such as saturated fat and fiber.

We found saturated fat intake to be more than twice that of the American Heart Association recommendation [30,31]. We speculate that, when reducing carbohydrate intake to control weight and hyperglycemia, participants appeared to have replaced the energy they previously got from carbohydrate with energy from fat. Further, participants did not choose to replace carbohydrates with the monounsaturated or polyunsaturated fats that have been shown to be cardioprotective. The ADA recommends a diet with <7% saturated fat content for people with diabetes [11,32]. It is well understood that saturated fat is one of the main factors contributing to elevation of low-density lipoprotein cholesterol, which can increase risk of cardiovascular disease and overall inflammation [33].

Table 2  
Dietary intake at baseline for participants in the Diabetic Educational Eating Plan study, Worcester, Massachusetts, 2005–2006

	Mean $\pm$ SD
Daily energy intake (kcal)	1778 $\pm$ 814
Daily CHO intake (g)	159 $\pm$ 71
%Energy (kcal) from CHO	36.73 $\pm$ 8.62
%Energy (kcal) from protein	19.67 $\pm$ 5.08
%Energy (kcal) from fat	44.60 $\pm$ 8.85
Type of fat	
%Energy (kcal) from saturated fat	14.45 $\pm$ 3.43
%Energy (kcal) from monounsaturated fat	17.49 $\pm$ 3.93
%Energy (kcal) from polyunsaturated fat	9.45 $\pm$ 3.12
Daily total fiber intake (g)	11.43 $\pm$ 5.18
Daily soluble fiber intake (g)	3.92 $\pm$ 1.81
Daily insoluble fiber intake (g)	7.38 $\pm$ 3.45
Dietary glycemic index	80.70 $\pm$ 5.42
Dietary glycemic load	133.62 $\pm$ 61.82

CHO, carbohydrate

Also against current recommendations, dietary fiber and, in particular, soluble fiber intakes were found lacking among study participants. For people without diabetes, total dietary fiber intake is recommended to be 14 g/1000 kcal each day, including soluble and insoluble fibers [34]; the recommended intake is higher for individuals with diabetes [11,32]. Dietary fiber intake is inversely associated with levels of C-reactive protein [35], a marker of inflammation predicting future coronary heart disease (CHD) [36–40]. Soluble fiber is also of benefit in lowering low-density lipoprotein cholesterol and is mainly found in whole grains such as barley and oats and in legumes, fruits, vegetables, nuts, and ground flax seeds. Insoluble fiber promotes normal bowel function, prevents constipation, and can be found in whole-grain bread, whole-grain breakfast cereals, wheat bran, seeds, and many vegetables. In addition, whole-grain carbohydrate foods (containing soluble and insoluble fibers) are a nutritious part of the diet, with vitamins and minerals essential to many physiologic functions.

Contrary to the ongoing popular trends to lower total carbohydrate for weight loss, it may prove to be more effective and better for overall health to distinguish between types of carbohydrate rather than to focus on total quantity. The association of GI, carbohydrate intake, and BMI was

Table 3  
Oral hypoglycemic medication use at baseline for participants in the Diabetic Educational Eating Plan study, Worcester, Massachusetts, 2005–2006

	Frequency (%)
Metformin	29 (72.5%)
Glyburide	15 (37.5%)
Glipizide	4 (10%)
Pioglitazone	6 (15%)
Rosiglitazone	3 (7.5%)
Repaglinide	1 (2.5%)

Table 4  
Insulin use at baseline for participants in the Diabetic Educational Eating Plan study, Worcester, Massachusetts, 2005–2006

	Frequency (%)
Long-acting: glargine	5 (12.5%)
Long-acting: ultra lente	2 (5%)
Intermediate-acting: NPH lente	7 (17.5%)
Rapid-acting: regular	2 (5%)
Rapid-acting: aspart	2 (5%)
Rapid-acting: lispro	3 (7.5%)
Premixed insulin: 70/30	1 (2.5%)

NPH, neutral protamine hagedorn.

investigated by our group using data from 563 healthy study participants in central Massachusetts [23,41]. BMI was found to be positively associated with the GI, a measurement of the glycemic response associated with the ingestion of different types of carbohydrate, but not with daily carbohydrate intake, percentage of energy from carbohydrate, or GL. If patients are attempting to lose weight, a low total carbohydrate intake goes against this finding. Choosing whole-grain carbohydrates rather than avoiding carbohydrate foods may be a wiser approach.

Dietary composition observed in the present study of people with diabetes diverges from the NHANES (U.S. general population) data. In a study of nutrient intake and eating frequency using data from the NHANES III (1988–1994), carbohydrate intake for U.S. adults was 44.9–51.1% of daily energy intake in kilocalories, whereas fat accounted for 32.7–36.7% of energy intake [42].

For historical comparison with the same geographic area as our present study, we draw from two of our previous studies in the mid-1990s [23,41,43], for which dietary data were collected using the same diet assessment methodology. Dietary composition was approximately 45% of energy from carbohydrate, 36% from fat, and 19% from protein (not far different from that of the NHANES covering the same time period). The study groups consisted of a predominantly overweight and hyperlipidemic population without diabetes of any type.

Our data agreed with the findings that patients with T2DM tend to have a lower carbohydrate intake than that of the general population. Eeley et al. [44] in 1996 reported a consumption of 43% of energy from carbohydrate in 132 adults with T2DM in the United Kingdom [44]. Ten years later, in 2006, our study population with T2DM consumed 36% of energy from carbohydrate, a significant decrease. A sampling of other observational studies dating back to 1980 indicates that the general population consumes, on average, between 40% and 50% carbohydrate content [45–49]. We have listed dietary composition in comparison with other populations and studies in Table 5.

There are several possible explanations for the dietary differences between our previous studies in patients without T2DM and the present study. First, the present study was conducted between 2005 and 2006, when low-carbohydrate

Table 5  
Summary of dietary composition from selected literature

Study	Years conducted	Study population	CHO intake	Fat intake (%)	Energy intake (kcal)
Present study	2005–2006	40 adults with type 2 diabetes in central Massachusetts	159 g (36%)	45%	1778
Ma et al. [41]	1994–1998	641 healthy adults in central Massachusetts	231.2 g (44.9%)	36.7%	2055
Kerver et al. [42]	1988–1994	15 978 American adults age $\geq$ 20 y (national data)	162–376 g (44.9–51.1%)	32.7–36.7%	1446–2940
Hebert et al. [43]	1991–1995	645 hyperlipidemic adults ages 20–65 y in central Massachusetts	201 g (43%)	36.2–40.2%	1846–1986
Eeley et al. [44]	1996	132 adults (mean age 55 y) with type 2 diabetes in United Kingdom	43%	37%	NA
Patterson et al. [45]	1995	16 741 women who joined Women's Health Initiative in 1995	180 g (48%)	34%	1493
Quatromoni et al. [46]	1984–1999	1828 women from Framingham Offspring/Spouse Study	147–197 g (38.5–45.7%)	36.7–41.7%	1530–1728
Millen et al. [47]	1984–1996	166 men from Framingham Offspring/Spouse Study	214–252 g (42.4–43.7%)	35.2–37.1%	2020–2309
Hu et al. [48]	1986	44,875 men ages 40–75 y without diagnosed cardiovascular disease	223–249 g	61–77 g/d	NA
Chiu et al. [49]	1980	526 women from Nurses' Health Study	198.5–202.6 g (45–47%)	NA	1698–1794

CHO, carbohydrate; NA, not available

diets and food options are not unusual [50]. According to consumer research in 2005 [51], 40% of U.S. adults reported that they had reduced their carbohydrate intake. Second, approximately 80% of the subjects from our present study were obese, recognized they had problems with weight, and had tried to lose  $\geq$ 10 lb in the previous year, possibly through an even stricter reduction of total dietary carbohydrate. Although the participants stated that they were not currently following a low-carbohydrate diet, this may have been in comparison with previous experience, and they may have retained many of the core components of the current popular trend. Third, our participants were also battling hyperglycemia, and the low-carbohydrate options that are readily available from the food supply offer an approach to glucose management.

Of the three macronutrients (carbohydrate, protein, and fat), carbohydrate intake has the greatest influence on blood glucose, although the overall balance of micro- and macronutrients has implications for diabetic complications. When diagnosed with T2DM, patients are generally instructed to carefully monitor their intake of carbohydrate and to distribute carbohydrate intake evenly throughout the day. Despite ADA recommendations, patients may find simple reduction of total carbohydrate easier than monitoring via the exchange system or distinguishing between types of carbohydrate.

The prevalence of obesity was higher in our sample (77.5%) compared with data from the NHANES 1999–2002 that recorded a 54.8% prevalence of obesity among adults diagnosed with diabetes [9]. Popular weight-loss regimens also have shifted since the NHANES study. Clearly, the low-carbohydrate diet for weight loss has become pop-

ular in the United States over the past several years and, although currently waning, has retained many of its central features [13,14].

In our sample, it is alarming to note that carbohydrate intake has been replaced with fat, especially saturated fat, and has also resulted in a low-fiber diet. It is widely accepted that diets high in saturated fat increase the risk of CHD [52–54], and there is a fairly broad-based consensus on the role of dietary fat (especially saturated fatty acids) in hyperlipidemia and on the role of hyperlipidemia in CHD. Patients with diabetes are particularly vulnerable to CHD. There is no doubt that the diabetic diet is a complex one (and time consuming for the busy clinician to devote time to instruction), yet the effect of reduction of total carbohydrate on other dietary factors, such as increased saturated fat and decreased dietary fiber, must be moderated by additional instruction to balance the diet toward one that is also heart healthy.

Limitations of the study include small sample size, which limits generalizability, and the fact that this analysis was a case-series rather than a case-control design. This study is a pilot trial designed to test the feasibility and efficacy of a low-GI diet in comparison with standard ADA recommendations; as such, it is not designed to compare nutrient intake between subjects with diabetes and subjects without diabetes. However, we did compare our data with the national sample (NHANES), two sample studies from the local population, one from subjects with T2DM in 1996, and a sample of other studies. We believe that our analysis of the study provides an important cautionary tale for clinicians and health professionals who treat T2DM. Additional limitations are possible inaccuracies in participants'

reported diet composition on the 7DDR [55] questionnaire. Although the 7DDR is fairly accurate in assessing total and saturated fat intakes, trans-fatty acid intake cannot be obtained. Strengths of the study include detailed information obtained about diet, blood lipids, comorbidities, and medication use.

## Conclusion

The current popular trend to lower carbohydrate intake may have serious future cardiovascular implications in this vulnerable population. If this eating pattern is found to be similar across the country and the rest of the world, this will have a large effect on the future health of patients with T2DM.

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