Prospective Randomized Controlled Trial to Evaluate Effectiveness of Registered Dietitian–Led Diabetes Management on Glycemic and Diet Control in a Primary Care Setting in Taiwan

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OBJECTIVE — In this randomized controlled trial we evaluated the effect of registered dietitian–led management of diabetes on glycemic control and macronutrient intake in type 2 diabetic patients in primary care clinics in Taiwan and studied the association between changes in macronutrient intake and glycemic measures.

RESEARCH DESIGN AND METHODS — We recruited 154 adult patients with type 2 diabetes and randomly assigned them to a routine care control group ($n = 79$) or a registered dietitian–led intervention group ($n = 75$) who received on-site diabetic self-management education every 3 months over 12 months.

RESULTS — Over the 1-year period, neither the intervention group ($n = 75$) nor the control group ($n = 79$) had significant changes in A1C, whereas the intervention patients with poorly controlled baseline A1C (≥7%) ($n = 56$) had significantly greater improvements in A1C and fasting plasma glucose than the control subjects ($n = 60$) (−0.7 vs. −0.2%, $P = 0.034$; −13.4 vs. 16.9 mg/dl, $P = 0.007$) during the same period. We also found significant net intervention-control group differences in overall energy intake (−229.06 ± 309.16 vs. 56.10 ± 309.41 kcal/day) and carbohydrate intake (−31.24 ± 61.53 vs. 7.15 ± 54.09 g/day) ($P < 0.001$) in patients with poorly controlled A1C. Multivariable adjusted modeling revealed an independent association between changes in carbohydrate intake and A1C in the intervention group ($n = 56$; $\beta = 0.10$, SEM = 0.033, $P = 0.004$).

CONCLUSIONS — On-site registered dietitian–led management of diabetes can improve glycemic control in patients with poorly managed type 2 diabetes in primary care clinics in Taiwan. A reduction in carbohydrate intake may improve glycemic status.

Diabetes Care 33:233–239, 2010

The World Health Organization has predicted that the number of people with diabetes will increase from 135 million in 1995 to 300 million by 2025 (1) with the greatest increases in Asia (2). The annual incidence of diabetes is 0.5–1.0% in Taiwan. There are at least 100,000 new cases per year (3) and 11.5% of total medical costs covered by Taiwan's national insurance is spent on the treatment of diabetes and its complications (4).

The Diabetes Control and Complications Trial and UK Prospective Diabetes Study (UKPDS) reported that the use of multidisciplinary approaches with the aim of making healthy changes in lifestyle can improve glycemic control and delay or reduce further complications, some by as much as 50–75% (5,6). Registered dietitians can contribute greatly to comprehensive care plans for diabetic patients, who as a result of dietary education, have been found to have improved anthropometric measures and glycemic control and use less prescribed medication (7,8). In addition, patients with chronic diseases, including diabetes, have been found to benefit from patient-centered approaches encouraging self-management of disease (9). Nevertheless, one study in the U.S. reports that more than half of the diabetic patients did not receive diabetic-related knowledge and self-management skills at their primary clinics and were not referred to relevant educational programs (10). In Taiwan, where the number of on-staff registered dietitians is determined by number of beds in hospitals, primary care clinics are not required to have registered dietitians on staff.

In this study, we hypothesized that patients receiving ongoing patient-centered consultation provided by a dietitian would be more likely to follow a diet designed to improve glycemic control than those not receiving such consultation. To find out, we first created a model through which physicians, dietitians, and nurses would cooperate to provide comprehensive individualized on-site patient care and registered dietitian–led self-management education. We then assessed the effect of this program on glycemic control and macronutrient intakes in 75 patients compared with 79 type 2 diabetic patients receiving the routine care practiced in their primary care setting.

RESEARCH DESIGN AND METHODS

— To choose participating clinics, we visited the public health

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Received 16 June 2009 and accepted 30 October 2009. Published ahead of print at http://care.diabetesjournals.org on 12 November 2009. DOI: 10.2337/dc09-1092. Clinical trial reg. no. NCT00288678, clinicaltrials.gov.

bureau of Kaohsiung, a city in southern Taiwan, to obtain clinics known for their care of diabetic patients. The investigators then visited clinics to find out their willingness to participate. Then, starting in May 2004, we recruited 154 patients with diagnosed or newly diagnosed type 2 diabetes aged between 30 and 70 years who were receiving treatment at five primary health care clinics. Type 2 diabetes was diagnosed by primary physicians based on criteria established by the American Diabetes Association (ADA) (11). Patients were excluded if they were pregnant or undergoing dialysis or if they had received an amputation or had comorbid blindness, systemic illnesses such as cancer or cardiovascular disease based on physician diagnosis of myocardial infarction or stroke on national insurance claim forms. If the subjects were eligible and willing to participate in this study, the primary physicians referred them to the registered dietitians. The registered dietitians explained the study to the participants and informed them that they would be randomly assigned to either a registered dietitian–led multidiscipline diabetes management group ($n = 75$) or a usual care group (control group) ($n = 79$). Once a participant signed an informed written consent form, he or she was enrolled in the study. The name, age, and sex of the enrollees were entered into a computer, which randomly assigned them in a 1:1 manner to control groups and intervention groups. The study protocol was approved by the institutional review boards of National Health Research Institutes/Taiwan and Kaohsiung Medical University Hospital.

Intervention program

Patients in the control group received the routine care practiced at their primary care, which may have also included a summary of basic dietary principles by nurses. Patients in the intervention group, in addition to receiving usual care, received ongoing instruction on the self-monitoring of glucose, medications, exercise, hygiene (foot care), and complication management (11) from two registered dietitians who had received additional clinical training in the Department of Endocrinology and Metabolism and the Department of Nutrition at the participating medical center. The patients in the intervention group were also provided individualized nutrition counseling and dietary plans to reinforce the concepts of controlling portion sizes of foods every 3 months. During each visit, which lasted 30–60 min, the registered dietitians assessed patients' understanding and practice of dietary plans and self-care skills and reinforced important knowledge throughout the study period. The physicians consulted with the registered dietitians based on medicines prescribed or patients' self-care related to adjustment of meal times and amount of food. The registered dietitians were also provided with a hospital-use mobile phone. The intervention patient could call the registered dietitians if he or she needed dietary advice, and the registered dietitians called the patients to help solve problems that patients might have encountered when trying to follow the diet.

Nutrition education program

During each intervention patient visit, the registered dietitians obtained daily nutrient intake by asking the patients to recall the foods consumed for the previous 24-h period, a method of inquiry routinely used in clinical settings in Taiwan. Nutrient intake was analyzed by nutrient analysis software (Nutrition Chamberlain Line, Nutritionist Edition, Enhancement version 2002, Ekitchen, Taichung, Taiwan). Each patient received dietary education recommended by the ADA (12). One goal was to avoid excessive energy intake and assure balanced nutrition by replacing high-fat with low-fat foods and consuming foods rich in fiber and micronutrients. A second goal was to introduce the concept of portion size of the six food groups to patients and emphasize the possible impact of portion size control, especially carbohydrate counting, on glycemic control. Food models resembling standard portion sizes for food groups were used to enhance the accuracy of diet-related information. An individualized diet plan was created to maintain intake of protein, fat, and carbohydrate energy to ~15–20, 25–30, and 50–60%, respectively, following the guidelines established by the ADA (12).

Measurement of clinical parameters

At baseline and at 1 year, anthropometric measurements and clinical laboratory measurements after an 8- to 12-h fast were obtained for both groups. In addition, both groups answered a registered dietitian–administered questionnaire regarding demographic characteristics and dietary habits. All clinical parameters were sent to a laboratory (Protech Pharmaservices, Taipei, Taiwan) certified by The College of American Pathology and U.S. Commission on Office Laboratory Accreditation. A1C assays were performed using high-performance liquid chromatography (Variant II; Bio-Rad, Hercules, CA). Fasting plasma glucose, cholesterol, triglyceride, LDL cholesterol, HDL cholesterol, uric acid, creatinine, and high-sensitivity C-reactive protein were analyzed by enzymatic assay using an autoanalyzer (Hitachi 7060; Hitachi, Tokyo, Japan). Medical charts were reviewed to obtain information regarding patient use of medications.

Statistical analysis

A t test was used to analyze differences in continuous variables between two groups. A χ^2 test or Fisher exact test (if $n < 5$) was used to analyze distribution of categorical variables. Simple linear regression was used to examine the relations between changes in A1C and changes in macronutrient intake (grams), and multiple linear regression was used to adjust for confounders. All statistical analyses were performed with SPSS (version 11.5). $P < 0.05$ was considered significant.

RESULTS

— Eighteen patients dropped out of the intervention group and 21 out of the control group by the 1-year follow-up, leaving us with 154 subjects. There were no significant group differences in age, sex, disease duration, and education in the 154 participants who remained (Table 1). We also found no significant difference in age, sex, disease duration, and education between the intervention ($n = 56$) and control ($n = 60$) patients with poor baseline glycemic control (A1C ≥7%) (Table 2).

Clinical parameters

We found no significant improvement in A1C between the 75 intervention and 79 control patients regardless of baseline A1C (Table 1), although we did find a significant improvement in the fasting plasma glucose intervention group compared with the control subjects ($P = 0.026$) (Table 1). The 56 subjects in the intervention group with poor baseline glycemic control had a greater reduction in mean A1C (0.7%) than the 60 control subjects (0.2%) ($P = 0.034$) as well as significantly greater improvements in fasting plasma glucose (−13.4 ± 55.2 vs.16.9 ± 63.6 mg/dl, $P = 0.007$) and systolic blood pressure (0.5 ± 16.8 vs. 8.6 ± 17.4 mmHg, $P = 0.012$) (Table 2).

Table 1—*Baseline characteristics and changes of clinical parameters in type 2 diabetic patients after receiving a 12-month intervention or usual care (control)*

	Baseline			Changes from baseline to 12 months		
	Intervention	Control	*P* value	Intervention	Control	*P* value
n	75	79		75	79	
Baseline characteristics						
Age (years)	56.6 ± 8.0	56.9 ± 7.5	0.802	—	—	—
Diabetes duration (years)	4.8 ± 4.4	4.8 ± 4.5	0.996	—	—	—
Male sex (%)	29 (38.7)	38 (48.1)	0.238	—	—	—
Education						
<6 years primary school	45 (60.0)	59 (74.7)	0.052	—	—	—
>6 years primary school	30 (40.0)	20 (25.3)		—	—	—
Clinical measurements						
Height (cm)	159.1 ± 8.3	161.1 ± 8.2	0.141	−0.1 ± 1.2	−0.1 ± 1.0	0.872
BMI (kg/m^2)	25.7 ± 3.2	27.0 ± 4.7	0.044	0.1 ± 1.2	0.2 ± 1.5	0.733
Systolic blood pressure (mmHg)	131.8 ± 19.8	134.9 ± 17.4	0.304	−0.7 ± 15.8	6.0 ± 18.9	0.019
Diastolic blood pressure (mmHg)	79.7 ± 10.5	84.2 ± 10.3	0.008	0.0 ± 11.0	0.6 ± 10.9	0.736
Glucose (mg/dl)	147.4 ± 49.6	159.7 ± 53.4	0.141	−6.8 ± 50.1	12.7 ± 56.9	0.026
A1C (%)	8.0 ± 1.5	8.4 ± 1.8	0.212	−0.5 ± 1.1	−0.1 ± 1.5	0.101
Triglyceride (mg/dl)	145.4 ± 90.2	164.6 ± 122.9	0.272	−3.8 ± 69.2	−0.3 ± 110.8	0.818
Total cholesterol (mg/dl)	183.0 ± 37.9	187.3 ± 38.4	0.488	−5.1 ± 39.3	0.3 ± 43.7	0.424
HDL cholesterol (mg/dl)	50.1 ± 12.2	48.7 ± 11.1	0.471	−0.1 ± 11.2	−0.6 ± 8.7	0.743
LDL cholesterol (mg/dl)	117.8 ± 33.4	118.5 ± 32.5	0.898	−6.0 ± 35.9	0.1 ± 36.3	0.297
GPT (units/l)	35.3 ± 26.5	40.1 ± 35.9	0.350	2.9 ± 44.6	−0.3 ± 25.0	0.582
Creatinine (mg/dl)	0.8 ± 0.3	0.8 ± 0.2	0.631	0.0 ± 0.4	0.0 ± 0.2	0.765
Uric acid (mg/dl)	5.5 ± 1.6	5.6 ± 1.9	0.670	0.5 ± 1.3	0.2 ± 1.7	0.235
hs-CRP (mg/dl)	0.4 ± 1.3	0.3 ± 0.3	0.693	−0.1 ± 1.5	−0.1 ± 0.4	0.790

Data are means + SD or *n* (%). A *t* test or χ^2 test was used to test differences between the intervention and control subjects at baseline. A *t* test was also used to determine the changes in clinical parameters between the two groups after a 1-year intervention. $P < 0.05$ is considered significantly different. GPT, glutamic pyruvic transanimase; hs-CRP, high-sensitivity C-reactive protein.

There were no significant group differences in medication usage either at baseline or at follow-up in patients with poor baseline glycemic control (Table 2; supplemental Table 1).

Dietary intake

In participants with A1C ≥7%, the intervention group had a mean decrease in energy intake of 229 ± 309.16 kcal/day, whereas the control group had a mean increase of 56.10 ± 309.41 kcal/day ($P < 0.001$). Over the 12-month period, there was a decrease in energy intake including overall reduction in absolute amounts (grams) of carbohydrates, fat, and protein in the intervention group (Table 3). Although the energy percent values of carbohydrate, fat, and protein at baseline and at the 1-year intervention were similar for both groups, the intervention group had significantly greater net reductions in saturated fat than the control group (−0.98 ± 3.40 vs. +0.60 ± 2.93, $P = 0.01$) (Table 3). In addition, there was a significant reduction in energy (kilocalories per day) and fat (grams per day) intake in those with A1C <7% compared with that in control subjects (data not shown).

Macronutrient intake and glycemic control

Our univariate analysis showed a correlation between changes in A1C and baseline BMI, baseline A1C, and changes in energy intake at per 100 kcal/day ($\beta = 0.200$, SEM = 0.041, $P < 0.001$) and carbohydrate intake at per 15 g/day ($\beta = 0.167$, SEM = 0.029, $P < 0.001$) in the intervention group with baseline A1C ≥7% (Table 4). After adjustment for age, sex, duration of diabetes, baseline BMI, and baseline A1C, we found an association between a 15-g increase in carbohydrate (one carbohydrate counting) intake and a 0.1% increase in A1C (SEM = 0.033, $P = 0.004$) but not in overall energy intake ($\beta = 0.04$, SEM = 0.04, $P = 0.310$) (Table 4).

CONCLUSIONS

— This study showed that the registered dietitian–led diabetes management program in the primary care clinics significantly improved the glycemic control of type 2 diabetic patients with baseline A1C ≥7%. We found a strong and independent association between a reduction in carbohydrate intake and improvements in A1C ($P < 0.001$). We observed a much greater reduction in A1C in our poorly controlled intervention group (0.7%) than in the control group (0.2%) ($P = 0.034$). Our intervention group also had a 13.4 mg/dl reduction in mean fasting glucose plasma, whereas our control group had a 16.9 mg/dl increase in that measure ($P = 0.007$).

Recently, some large randomized controlled trials have also documented the effectiveness of lifestyle or nutrition interventions on delaying the progression from impaired glucose tolerance to diabetes in high-risk individuals (13,14). However, most of those studies were based on patients receiving care in academic or medical centers with more departments and greater capacity to provide individualized nutrition counseling than primary care clinics. Although there have been studies on the management of diabetes in primary care (15), none have studied the effect of the kind of registered dietitian–led management of diabetes on glycemic and diet controls that was proposed in this study.

The effects of diabetic self-management education focusing on dietary or lifestyle changes have been reported in some trials in primary care settings

Table 2—*Baseline characteristics and changes of clinical parameters and medication in type 2 diabetic patients with baseline A1C ≥7% after receiving a 12-month intervention or usual care (control)*

	Baseline			Changes from baseline to 12 months		
	Intervention	Control	*P* value	Intervention	Control	*P* value
n	56	60		56	60	
Baseline characteristics						
Age (years)	55.8 ± 8.2	57.4 ± 7.5	0.286	—	—	—
Diabetes duration (years)	5.2 ± 4.5	5.5 ± 4.7	0.665	—	—	—
Male sex (%)	23 (41.1)	31 (51.7)	0.253	—	—	—
Education						
<6 year primary school	34 (60.7)	45 (75.0)	0.099	—	—	—
>6 year primary school	22 (39.3)	15 (25.0)		—	—	—
Medication use						
Glucose-lowering treatment						
Sulfonylurea	54 (96.4)	57 (95.0)	1.000	—	—	—
Biguanide	45 (80.4)	50 (83.3)	0.677	—	—	—
Thiazolidinedione	7 (12.5)	14 (23.3)	0.130	—	—	—
Other oral hypoglycemia agent	0 (0.0)	2 (3.3)	0.496	—	—	—
Lipid-lowing treatment						
Gemfibrozil	2 (3.6)	0 (0.0)	0.231	—	—	—
Statins	21 (37.5)	13 (21.7)	0.061	—	—	—
Fibrate	0 (0.0)	1 (1.7)	1.000	—	—	—
Antihypertensive treatment						
Diuretics	1 (1.8)	2 (3.3)	1.000	—	—	—
β-Blocker	0 (0.0)	2 (3.3)	0.496	—	—	—
α-Blocker	1 (1.8)	1 (1.7)	1.000	—	—	—
Calcium-channel blocker	17 (30.4)	20 (33.3)	0.731	—	—	—
ACE inhibitor	7 (12.5)	9 (15.0)	0.696	—	—	—
Angiotensin receptor blocker	4 (7.1)	7 (11.7)	0.531	—	—	—
Aspirins	4 (7.1)	8 (13.3)	0.365	—	—	—
Clinical measurements						
Height (cm)	159.3 ± 8.2	161.2 ± 8.4	0.206	−0.1 ± 1.3	−0.2 ± 1.0	0.769
BMI (kg/m^2)	25.7 ± 3.2	26.8 ± 4.2	0.093	0.2 ± 1.3	0.2 ± 1.3	0.953
Systolic blood pressure (mmHg)	132.4 ± 20.9	134.3 ± 18.9	0.627	0.5 ± 16.8	8.6 ± 17.4	0.012
Diastolic blood pressure (mmHg)	80.1 ± 10.5	84.2 ± 10.4	0.038	0.6 ± 11.5	0.4 ± 10.0	0.945
Glucose (mg/dl)	160.8 ± 49.6	173.7 ± 52.7	0.178	−13.4 ± 55.2	16.9 ± 63.6	0.007
A1C (%)	8.6 ± 1.2	9.0 ± 1.5	0.087	−0.7 ± 1.1	−0.2 ± 1.7	0.034
Triglyceride (mg/dl)	157.9 ± 97.7	161.8 ± 126.2	0.856	−9.7 ± 67.9	3.6 ± 111.8	0.445
Total cholesterol (mg/dl)	183.8 ± 38.1	191.5 ± 39.4	0.290	−5.8 ± 38.9	−0.3 ± 44.7	0.485
HDL cholesterol (mg/dl)	48.4 ± 10.7	47.8 ± 11.2	0.778	0.6 ± 10.6	0.0 ± 8.1	0.734
LDL cholesterol (mg/dl)	119.5 ± 32.0	123.5 ± 32.3	0.500	−7.3 ± 35.1	−1.9 ± 37.2	0.430
GPT (units/l)	37.6 ± 27.5	38.8 ± 34.5	0.840	−2.8 ± 18.1	0.0 ± 22.9	0.468
Creatinine(mg/dl)	0.8 ± 0.3	0.8 ± 0.2	0.662	0.0 ± 0.4	0.0 ± 0.2	0.883
Uric acid(mg/dl)	5.5 ± 1.6	5.6 ± 2.1	0.819	0.5 ± 1.3	0.3 ± 1.8	0.451
hs-CRP (mg/dl)	0.5 ± 1.5	0.3 ± 0.3	0.540	−0.1 ± 1.8	−0.1 ± 0.3	0.908

Data are means ± SD or *n* (%). A *t* test or χ^2 test (Fisher test was used as $n < 5$) was used to test differences between the intervention and control subjects at baseline. A *t* test was also used to determine the changes in clinical parameters between the two groups after a 1-year intervention. $P < 0.05$ is considered significantly different. GPT, glutamic pyruvic transanimase; hs-CRP, high-sensitivity C-reactive protein.

(16,17). The results of those studies showed the intervention groups to have greater reductions in A1C (−0.92 to −1.8%) than the control groups (−0.16 to −0.4%). In one French study using the Staged Diabetes Management Program (18) in a primary care setting, the intervention group had a 0.31% decrease in A1C, whereas the control group had a 0.56% increase, which made an overall difference of 0.86%. The intervention group in this study had improvements comparable in magnitude to those reported by other trials (16–18) as well as to those reported by the UKPDS study, which reported a 1% decrease in A1C for the invention group and a 0.1% increase in the control group (6). Another study of a French population also demonstrated that by introducing a diabetic management program, glycemic control can be improved without increasing the total health care cost (18).

In this study, we tried to identify how on-site nutrition counseling would affect not only glycemic control but also adherence with dietary recommendations and self-management of disease in a primary care setting. Although this study showed no differences in A1C when the two

Table 3—*Changes in nutrient intakes in type 2 diabetic patients with baseline A1C ≥7% after receiving a 12-month intervention or usual care (control)*

	Baseline			Changes from baseline to 12 months		
Nutrient intakes	Intervention	Control	*P* value	Intervention	Control	*P* value
	56	54		56	54	
Energy (kcal/day)	1,899.0 ± 399.8	1,877.5 ± 405.3	0.778	−229.06 ± 309.16	56.10 ± 309.41	<0.001
Carbohydrates						
Energy %	54.4 ± 7.9	54.4 ± 8.5	0.999	0.01 ± 9.29	−1.01 ± 7.64	0.530
g/day	256.4 ± 58.8	245.0 ± 45.1	0.250	−31.24 ± 61.53	7.15 ± 54.09	0.001
Protein						
Energy %	14.9 ± 2.8	14.8 ± 3.5	0.786	−0.52 ± 3.60	0.12 ± 3.50	0.345
g/day	70.4 ± 18.3	68.4 ± 24.6	0.622	−10.91 ± 18.85	2.94 ± 18.60	<0.001
Fat						
Energy %	30.6 ± 6.7	30.8 ± 6.9	0.899	0.51 ± 7.92	0.89 ± 7.20	0.793
g/day	64.8 ± 21.0	63.3 ± 22.4	0.712	−7.74 ± 18.36	3.84 ± 19.99	0.002
Monounsaturates (%)	9.7 ± 3.0	10.0 ± 3.7	0.686	0.61 ± 3.91	1.00 ± 3.70	0.596
Polyunsaturates (%)	10.9 ± 3.0	11.0 ± 3.7	0.852	−0.05 ± 4.47	−0.65 ± 4.83	0.500
Saturates (%)	8.7 ± 3.1	7.8 ± 2.9	0.141	−0.98 ± 3.40	0.60 ± 2.93	0.010
Cholesterol (mg/day)	237.3 ± 176.7	234.6 ± 178.9	0.935	−3.59 ± 200.15	14.97 ± 223.45	0.647

Data are means ± SD. A *t* test was used to test differences between the intervention and control subjects at baseline. A *t* test was also used to determine the changes in nutrient intakes between the two groups after a 1-year intervention. There were four subjects with missing dietary data at 1-year follow-up in the control group ($n = 54$). $P < 0.05$ is considered significantly different.

groups were considered as a whole, it should be noted that in our study the patients in the intervention group with fair baseline A1C (<7%) had significantly greater reductions in fasting plasma glucose and intake of energy (kilocalories per day) and fat (grams per day), but not in overall change in A1C, compared with control subjects. This finding provides valuable information for future diabetes care.

Imparting knowledge about nutrition to patients is essential when one is teaching diabetic patients how to self-manage their diseases (11). Previous studies analyzing data by the India Health Service Diabetes Care and Outcome Audit of 7,490 medical charts showed that patients receiving clinical nutrition education from a registered dietitian or a registered dietitian along with another staff member had greater improvements in A1C levels (−0.26 and −0.32%, respectively) than those receiving nutrition education from either a non–registered dietitian staff member or no nutrition education (−0.19 and −0.10%, respectively) (19). Furthermore, one study entitled the Improving Control with Activity and Nutrition Study, which randomly assigned obese type 2 diabetic patients to a registered dietitian–led case management group and a usual care group, reported that their registered dietitian–led case management group had greater reductions in weight, waist, A1C, and use of prescription medication than the control subjects (20). To our knowledge, the current study is the first in Taiwan to demonstrate that effective glycemic control can be achieved by interventions by registered dietitians providing both diabetic self-management education and intensive dietary counseling in a primary care setting. After 1 year, energy intake had decreased by 229 ± 309.16 kcal/day in the intervention group but increased by 56.10 ± 309.41 kcal/day in the control group with A1C ≥7%. We also found concomitant reductions in the intake of absolute amounts of all three macronutrients in our intervention group. However, despite the significant reduction in total energy intake, we did not find significant reductions in body weight in the intervention group. The lack of weight loss in the intervention group might have occurred because most diabetic patients were taking a sulfonylurea drug, which stimulates storage of glycogen and lipogenesis. It has been well documented that the use of

Table 4 —*Univariate and multivariate regression analysis of factors associated with changes of A1C in intervention subjects with baseline A1C ≥7% after receiving a 12-month intervention*

	Simple linear regression		Multiple linear regression	
	β (SEM)	*P* value	β (SEM)	*P* value
Age (years)	−0.031 (0.018)	0.096	−0.013 (0.12)	0.304
Sex	−0.252 (0.304)	0.411	−0.367 (0.205)	0.080
Duration of diabetes (years)	−0.016 (0.033)	0.641	0.027 (0.023)	0.232
Baseline BMI	0.104 (0.045)	0.026	0.042 (0.032)	0.200
Baseline A1C (%)	−0.606 (0.093)	<0.001	−0.454 (0.084)	<0.001
Change in energy intake (100 kcal/day)	0.200 (0.041)	<0.001	0.045 (0.043)	0.303
Change in carbohydrate intake (15 g/day)	0.167 (0.029)	<0.001	0.100 (0.033)	0.004
Change in fat intake (15 g/day)	0.002 (0.124)	0.988	—	—
Change in protein intake (15 g/day)	0.188 (0.118)	0.117	—	—

$n = 56$.

these drugs is often associated with weight gain (6).

Most randomized controlled trials evaluating the effectiveness of diabetes-self management or lifestyle education have reported improvements in clinical indexes (5–6,16–18), but few have documented dietary changes (21,22). One study (21) using lifestyle education in diabetic patients reported significant differences in reductions in total fat (percent energy, $P < 0.001$) and saturated fat (percent energy, $P = 0.001$) and nonsignificant ($P = 0.13$) decreases in the total energy intake between their intervention and control groups (−215 vs. −144 kcal/day, respectively). Another randomized controlled trial (22), evaluating the effect of a weight reduction (including dietary counseling) and exercise program on diabetes management in older overweight patients, reported significant net differences in total energy intakes over 3 months (control 210.9 kcal/day, intervention −200.4 kcal/day, and net difference −411.3 kcal/day). However, these studies did not examine simultaneous association between changes in dietary components and metabolic parameters. Our study showed that energy intake was decreased by 229 ±+ 309.16 kcal/day in the intervention subjects and increased by 56.10 ± 309.41 kcal/day in the control subjects with A1C ≥7% ($P < 0.001$) after 1 year. Significant net differences were also observed between the absolute amounts (grams per day) of carbohydrate/fat/protein consumption in the intervention group (−31.24/−7.74/−10.91) and the control group (7.15/3.84/2.94). After adjustment for confounders, independent associations were found between changes in carbohydrate intake and A1C, indicating that carbohydrates may be the most important among macronutrients in influencing changes in A1C. This finding is consistent with the finding that the amount of carbohydrates consumed is a strong predictor of glycemic response (23). Therefore, portion size control or carbohydrate counting such as those suggested by the ADA may remain a key dietary strategy in achieving desirable glycemic control. Registered dietitians can play an important role in imparting this knowledge to diabetic patients and in helping them implement changes in diet.

There are some limitations in the current study. Twenty-four-hour dietary recall is commonly used in routine clinical nutrition counseling to estimate the food intake of patients in Taiwan. Although 24-h recall has been found to be confounded by recall bias (24), interviews of patients by trained dietitians who are able to retrieve more accurate dietary information may attenuate such errors. In addition, because both groups were likely to have recall bias, the rates of underreporting are probably comparable. Second, we did not analyze insulin sensitivity at baseline and only began doing it after the 1-year follow-up (unpublished data). Therefore, the present study did not report changes in insulin sensitivity after intervention was started.

In summary, we found that the registered dietitian–led diabetes management program aimed to increase a diabetic patient's knowledge of how to self-manage his or her illness was an effective strategy for controlling glycemic status and improving dietary habits for patients with poorly controlled type 2 diabetes. Changes in carbohydrate intake were independently associated with improvements in glycemic control, emphasizing the need for carbohydrate counting in nutrition education programs for diabetic patients.

Acknowledgments— This project was supported by grants funded by the National Health Research Institute (96A1-HDPP08-017) of Taiwan.

No potential conflicts of interest relevant to this article were reported.

Parts of this study were presented in abstract form at the annual meeting of the Federation of American Societies for Experimental Biology, New Orleans, Louisiana, 18–23 April 2009.

We thank the general practitioners (Dr. Chieh-Cheng Lin, Dr. Peng-Chu Chuang, Dr. Chieh-Huang Lu, Dr. Lai-Fu Chuang, Dr. Ming-Jung Han, and Dr. Fu-Hua Yen) and the diabetic patients who participated in this study for their enthusiastic support. We also extend our deep appreciation to Pei-Yi Sun, RD, for her professional assistance in coordinating and educating patients and Yi-Ching Sung and Huei-Ru Jhang for their technical assistance.

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