- PRACTICE PROJECTS

Implementing Evidence-Based Nutrition Practice Guidelines for Type 2 Diabetes Mellitus in Lebanon

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Lebanon is a Middle Eastern country experiencing a surge in the prevalence of type 2 diabetes mellitus among adults. This pilot study evaluated the feasibility and outcomes of implementing the Academy of Nutrition and Dietetics Evidence-Based Nutrition Practice Guidelines (EBNPGs) as part of medical care for patients newly diagnosed with type 2 diabetes mellitus. Seventy-five patients were recruited from 3 Lebanese hospitals, received nutrition care according to EBNPGs, and were followed up for 12 months. Patients achieved significant improvement in clinical outcomes between baseline and 3, 6, and 12 months. Further research is recommended to confirm the benefits of using EBNPGs. **Key words:** clinical outcomes, Lebanese patients with type 2 diabetes, medical nutrition therapy, therapeutic lifestyle changes, type 2 diabetes nutrition management

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N.Y. was the lead dietitian responsible for the manuscript preparation, data collection, and study coordination and data analysis. M.K., T.S., and R.Y. were senior dietitians (diabetes specialists) responsible for patients' recruitment, nutrition counseling, and education. M.Z. reviewed the study protocol and was the endocrinologist physician consultant. E.M. was the grant receiver/principal investigator and provided face-to-face training sessions on the implementation of the Academy medical nutrition therapy protocol for T2DM, and contributed to statistical analysis and final draft review. All authors read and approved the final manuscript.

The authors declare that they have no competing interests. Esther Myers was employed by the Academy of Nutrition and Dietetics at the time of the research.

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► LOBALLY, diabetes is expected to be the seventh leading cause of death by the year 2030.1 According to the World Health Organization, 9% of the world's adult population, aged 18 and older, had diabetes in 2014.¹ Of those affected by the disease, 77% were living in low- and middle-income countries, with the greatest number of individuals between the ages of 40 and 59 years.¹ Recently, the International Diabetes Federation projected that the global prevalence of diabetes among adults will rise from 387 million in 2014 to 592 million by the year 2035, which is about 10.1% of world's adult population.^{2,3} The highest increase is expected to be in the Middle East, and the biggest impact is expected to be on adults of working age.⁴ The International Diabetes Federation projected that 68 million people in the Middle East and North Africa regions will have diabetes by the year 2035 compared with 37 million in 2014.2 This is a nearly a 2-fold increase in the prevalence of diabetes among adults in the Middle East and North Africa regions.⁵ Factors such aging, family history, ethnicity, obesity, and physical inactivity contribute to the diabetes epidemic.^{1,3,5} Type 2 diabetes mellitus (T2DM) accounted for about 90% of all diagnosed cases of diabetes worldwide.1

As part of the Middle East, Lebanon is experiencing a rapid increase in the prevalence of diabetes. ^{4,5} In 2014, diabetes affected 14.4% of adults, 20 years and older. ⁵ The highest proportions of diabetes were found among adults 40 years and older. ⁵ In Greater Beirut, the combined prevalence of previously diagnosed and newly diagnosed diabetes was 15.8%. ⁴

The increase in the prevalence of T2DM and prediabetes among Lebanese adults paralleled a rise in obesity, physical inactivity, and complications because of uncontrolled diabetes. ^{6,7} Low levels of physical activity and obesity were identified as 2 major factors behind this epidemic. ⁸ Accordingly, adoption of lifestyle changes such as a decrease in caloric intake and an increase in physical activity was recommended to minimize the burden of diabetes and its associated complications. ^{9,10}

In addition to medication and other lifestyle changes, nutrition is an important aspect of prediabetes and diabetes management. 11-16 Patients need to be aware of and choose healthy foods to be able to manage their blood glucose. Thus, providing patients with individualized nutrition education and counseling is paramount for diabetes management. In Lebanon, patients with diabetes receive nutrition information from dietitians as well as physicians.

Each hospital usually has its own nutritional protocol and policy. There is no uniform protocol among dietitians for patients' nutrition care planning. For many dietitians in developing countries, the Academy of Nutrition and Dietetics (Academy) serves as a reference for those seeking nutrition guidelines and nutrition information. The guidelines are based on the best evidence available and identify the magnitude of expected outcomes that may be possible in 2 different ways: the percentage change in the baseline value and whether the patient can achieve the target goal. Development of evidence-based guidelines is time- and resource-intense. Thus, it is not practical, nor necessarily desirable, for each country or region to develop its own evidence-based nutrition practice guidelines.

In the United States and other countries, the use of the Academy Evidence-Based Nutrition Practice Guidelines (EBNPGs) for T2DM as part of medical care resulted in significant improvement in glycemic control and lifestyle clinical indicators in patients with type 2 diabetes. 17-19 However, it is unclear whether these guidelines, developed by and for dietitians practicing in the United States, will yield similar results when used in Lebanon. It has a different health care system, culture, and patient population. Therefore, the objective of this study was to assess the changes in the glycemic control and metabolic outcomes in patients newly diagnosed with T2DM in Lebanon after receiving nutrition counseling provided by dietitians who were trained to use the Academy EBNPGs as part of their medical care. In addition, results should be compared with the expected clinical outcomes

and target goals outlined in the EBNPGs protocol. This pilot study was designed to provide some understanding of the universal use of guidelines for improving patients' glycemic control and promoting consistency in diabetes management/nutrition care among dietitians.

PROCEDURES

Design

The design of this pilot study is a descriptive pre-/poststudy. It is an outcome-monitoring study that used practice-based research to assess common health outcome indicators *before* and *after* nutrition counseling sessions (an intervention) provided by registered dietitians to newly diagnosed patients with T2DM as part of diabetes management. As such, this study has no control arm or standardized patient control group for comparative purposes.

The study and the subject consent form were approved by the Institutional Research Board at Notre Dame University and accepted by all participating dietitians. Patients who agreed to participate in the study were asked to sign a consent form in accordance with the Helsinki Declaration and were provided with a numerical code to maintain confidentiality.

The sample was 100 newly diagnosed patients with T2DM recruited from 3 Lebanese hospitals. Seventy-five patients consented to be in the study and were followed up for 12 months. The nutrition therapy intervention was conducted according to the Academy EBNPGs protocol for patients with T2DM, ¹⁶ including in-depth nutrition counseling sessions to help patients establish goals for improving their dietary intake, applying core concepts of healthy lifestyle habits, and using blood glucose self-monitoring as part of diabetes self-management.

Participants and recruitment Dietitians' recruitment

Six Lebanese dietitians participated in this project. A dietitian with a PhD served as the

lead dietitian or study coordinator. The lead dietitian recruited 5 dietitians who were in practice from 3 large hospitals in Lebanon. Three dietitians had masters' degrees, and all of them had been practicing as diabetes specialists for at least 10 years (ranging from 10 to 18 years). The lead dietitian met with the 5 dietitians to explain the study protocol. Academy personnel provided intensive, faceto-face training sessions to all the study dietitians on the implementation of the Academy medical nutrition therapy (MNT) protocol for T2DM. Also, the dietitians were trained on how to read and use glucometers.

Patients' recruitment and dietitian visit

Each dietitian recruited 20 patients who were newly diagnosed with T2DM but had not received any nutrition counseling within the 12 months before enrollment in the pilot. Patients were recruited through the diabetes outpatient clinics at 3 hospitals (Saint George Hospital, Rizk Hospital, and Notre Dame Hospital). Inclusion criteria were the following: patients had to be newly diagnosed with T2DM and must not have received a dietitian consultation within the previous 12 months; they had to be 20 years or older; had received approval from their physicians to enter the study; and could not have planned surgery within the study period. Exclusion criteria included recent surgery, acute or chronic renal failure or complications, pregnancy, not currently taking insulin, or have severe complications because of diabetes. Recruitment of patients occurred during their visits to the diabetes clinic.

To minimize selection bias, dietitians approached the first 2 patients with T2DM arriving at the clinic during each day, with a goal of recruiting 20 patients within a 2-week time frame. Patients who agreed to participate in the study signed a consent form and were provided with a numerical code to maintain confidentiality. Also, patients received glucometers and testing strips for the entire duration of the project. Patients' counseling sessions were conducted according to the Academy protocol. ¹⁶ Each patient had 5 visits (first visit

at baseline, second visit at 2–3 months, third visit at 4 months, fourth visit at 6 months, and the last visit at 12 months). The duration of the initial visit ranged from 30 to 45 minutes, and follow-up visits were about 15 to 20 minutes each. At each counseling visit, participating patients received individualized therapeutic lifestyle intervention focused on healthy eating habits and self-management on the basis of the Academy EBNPGs protocol.

Data collection and measures

Participating dietitians captured data as outlined in the Academy EBNPGs protocol forms for T2DM during their nutrition counseling sessions. The Nutrition Progress Note Form, presented in Figure 1, was used to collect patient data.¹⁶ The anthropometric, biochemical, and subjective measure parameters identified on the form were obtained at each patient's visit. Anthropometric measurements included actual weight, height, and body mass index (BMI). Biochemical and clinical measures included glycosylated hemoglobin (HbA_{1C}), low-density lipoprotein (LDL), high-density lipoprotein (HDL), serum triglyceride, and blood pressure (systolic/diastolic), collected from the patients' medical charts. Subjective measures included the dietitian's assessment of dietary intake and eating habits (food preparation and meal planning, eating away from home, recipe modification), alcohol use, physical activity, self-monitoring of blood glucose, smoking habits, and knowledge of food/drug interaction. All patients received face-to-face counseling sessions during their visits. Patients' clinical measurements obtained at the 5 visits were compared with expected outcomes identified on the Academy of Nutrition and Dietetics Nutrition Progress Note Form. 16

In addition, dietitians recorded their assessment of patients' dietary and lifestyle changes using the form provided in the EBNPG toolkit for therapeutic lifestyle changes, such as cooking methods, meal planning, modifying recipes, restaurant selection, alcohol intake, smoking cessation, exercise, comprehension of healthy eating principles, receptively, and

adherence to the nutrition protocol. A 5-point Likert scale ranging from 1 (never demonstrated) to 5 (consistently demonstrated) was noted during patients' visits over the 12-month study period. ¹⁶

Statistical analysis

Statistical analyses were performed using the SAS 9.1 software (SAS Institute Inc, Cary, North Carolina). Analysis of variance was used to identify differences in the patients' measurements compared with baseline. Results of the clinical measurements were expressed as means ± standard deviation. Behavioral therapeutic lifestyle changes data were reported as median, and the Wilcoxon signed ranks test was used to assess differences between baseline values and values at 3, 6, and 12 months. The Pearson correlation coefficient was used to assess the associations between clinical data. The association between therapeutic lifestyle changes and clinical data was determined using the Spearman correlation coefficient. All reported P values were made on the basis of 2-sided tests and compared with a significance level of 5%.

FINDINGS

Participants' characteristics

Out of 100 newly diagnosed patients with T2DM recruited for this project, 75 (39 female, 36 male) consented to participate and completed visit 1, 73 completed visits 2 and 3, 65 completed visit 4, and 46 (29 female, 17 male) completed visit 5. The main reason for patients' dropping out was that some patients left the study because of place dislocation. They were not able to meet with their dietitians (25 patients). Also, 4 patients were not interested in measuring and self-monitoring their blood glucose and dropped out of the study. There were no significant differences in demographics for the patients who were completers versus noncompleters.

At enrollment, more than two-thirds of the patients were 51 years and older, with a mean age of 55 years (Table 1). Patients' mean BMI

NUTRITION PROGRESS NOTES

Type 2 Diabetes Mellitus

Client's Name:
Phone Number:
Medical Record #:
DOB: Gender:
Etheric Record #:
DOB: Gender:
Etheric Record #:
DOB: Reference (Octional): Reference Physician:

Other Diagnosis:					(Optional):	Referring Pt		
Expected outcome	(ii mana verb	meet ntervent igement cli alizes/de	provide goal ion = se training ent smonstr	lf- plus ates)	(✓ indicates Co	goal reached: **8 impliance Potentia	reached ehavioral Outcom Il Circle number 1	to 5)
Encounters	(80-90	(30-45	(30-45	(30-45	Date:	Dute:	Date	Date:
Encounters	min)	(min)		min)	1	2	3	4
Clinical Outcomes	E-20030	1000000	25000000	170000000	Value	Value	Value	Value
Preprandial blood glucose (mg/dL)	2				-	-	-	-
Bedtime blood glucose (mg/dL)								
A1C (%)								
SMBG. % in target range			=					
LDL-C (mg/dL)								
HDL-C (mg/dL)								
Triglycerides (mg/dL)								
Microalbumin (mcg/24 hr)								
Blood pressure					1	1	1	7
Height Weight/BMI								
Hypo/hyperglycemic episodes					x/mo	x/mo	x/mo-	x/mo
MNT Goel keal g CHO total g CHO/meal % Fat Adhere to appropriate meal pattern, exercise, and medication treatment, plan to maintain blood glucose and lipids within normal limits					kcal g CHO total g CHO	total	kcal g CHO total g CHO meals	kcal g CH(total g CH(meals
Behavioral Outcomes					% fat	% fat	% fat	% fat
Eats meals/snacks at appropriate times					12345	12345	12345	12345
Chooses food and amounts per meal plan					12345	12345	12345	12345
Verbalizes sick-day management skills					12345	12345	12345	12345
Manages signs and symptoms of hypoglycemia					12345	1 2 3 4 5	12345	12345
Accurately reads food labels					12345	12345	12345	12345
 Uses modified or modifies recipes to \(\Psi \) total fat/saturated fat/sodium 					1 2 3 4 5	1 2 3 4 5	12345	12345
Uses healthy cooking techniques					12345	12345	12345	12345
Selects appropriately from restaurant menu					12345	1 2 3 4 5	12345	1 2 3 4 5
Participates in aerobic activity per exercise prescription					1 2 3 4 5 —— x/wk	1 2 3 4 5 x/wk	1 2 3 4 5 x/wk	1 2 3 4 5 —— x/wk
Limits alcohol use to 1-2 drinks/day					1 2 3 4 5 svg	1 2 3 4 5 svg	12345	1 2 3 4 5 svg
Verbalizes importance of smoking cessation					12345	1 2 3 4 5	12345	12345
Modifies medication/food for activity/ lifestyle					12345	1 2 3 4 5	12345	12345
Verbalizes potential food/drug interaction Drug					1 2 3 4 5 dose	1 2 3 4 5 dose	1 2 3 4 5 dose dose	1 2 3 4 5 dose
Overall Compliance Potential*								
Comprehension					12345	12345	12345	12345
Receptivity					12345	1 2 3 4 5	12345	12345
Adherence					12345	12345	12345	12345

Intervention: D-Discussed. R-Reinforced/Reviewed, = Not reviewed,
 Outcome achieved, N/A Not applicable.

 "Key for Behavioral outcomes and Compliance Potential and Overall Adherence Potential: 1=Never demonstrated, 2=Rarely demonstrated, 3=SomeSimes demonstrated, 4=Often demonstrated, 5=Consistently demonstrated

 Copy form for more encounters

Copy form for more encounters

American Dietetic Association Medical Nutrition Therapy Evidence Based Guides for Practice @ 2001, The American Dietetic Association

Figure 1. Nutrition progress notes.

was 31.7 ± 4.9 kg/m² in the obese category, and the mean body weight was 83.6 ± 15.0 kg (Table 1). Three-day food records were used to estimate calorie intakes. Patients were asked to record everything they ate and drank

for 3 days, selecting the days that represent their usual eating patterns (2 weekdays and 1 weekend day). The average caloric intake of the 3-day food log was 1561 ± 428.9 kcal, mean of 48.7% carbohydrates and 32.2% fat

Table 1. Characteristics of the Participating Patients at Enrollment $(N = 75)^a$

Characteristics	Mean \pm SD
Age, y	55 ± 10.7
BMI, kg/m ²	31.7 ± 4.9
Weight, kg	83.6 ± 15.0
Caloric intake/d ^b	1561 ± 428.9

Abbreviations: BMI, body mass index; CHO, carbohydrate; SD, standard deviation.

(Table 1). Caloric intakes between visits are summarized in Table 2. Compared with baseline values, there was a slight reduction in energy intake, carbohydrate consumption, and fat intake at the second (at 2–3 months) and third (at 4 months) visits. No changes were observed at the fourth visit (at 6 months).

Medication usage was based on their usual medical care for controlling T2DM, as shown in Table 3. The most common medication was Metforman (43%) followed by NPH insulin, thiazolidinedione, and insulin Humulin (17.1%) and sulphonylurea (13.1%). Although patients taking insulin were not recruited into the study, many patients received insulin at some point during the treatment period. Other medications were not collected systematically.

Table 3. Medication Use Among Patients During the Study Period

Medication	Patients Treated With
	70
Insulin Humulin 70/30	17.1
Insulin Mixtrad 30	2.6
Total insulin NPH	19.7
Insulin Lantus	1.3
Total insulin	21
Diamicron	5.3
Amaryl 4 mg	3.9
Amaryl 2 mg	3.9
Total sulphonylurea	13.1
Glucophage 850 mg	43.4
Total metformin	43.4
Avandia 4 mg	17.1
Total thiazolidinedione	17.1
Glucobay	2.6
Others	2.8

Patients' clinical characteristics at baseline versus 12 months

Compared with baseline, patients' clinical parameters were significantly improved at the 12-month follow-up. The baseline mean level of HbA_{1C} (9.1%) was significantly reduced to 7.4% at 12 months (P < .0001) (Table 4). Likewise, patients' mean values of LDL-cholesterol and triglycerides were significantly reduced

Table 2. Participants' Caloric Intake, Carbohydrate Consumption and Fat Percentage, and Percent Reduction From Baseline by Visit

Visit	Caloric Intake, kcal Mean ± SD	Carbohydrates, g Mean \pm SD	Fat, % Mean ± SD
Visit 1	1561.1 ± 428.9	190.2 ± 55.9	32.2 ± 7.75
Visit 2	1471.7 ± 345.4	186.8 ± 44.1	30.5 ± 5.32
↓ from baseline, %	0.02 ± 0.21	-0.04 ± 0.32	0.03 ± 0.14
Visit 3	1473.2 ± 283.4	186.1 ± 41.8	30.7 ± 5.04
↓ from baseline, %	0.01 ± 0.18	-0.04 ± 0.29	0.03 ± 0.16
Visit 4	1486.9 ± 286.3	186.3 ± 44.1	30.5 ± 5.58
↓ from baseline, %	-0.0 ± 0.2	-0.07 ± 0.34	0.04 ± 0.17
Visit 5	1558.1 ± 382.7	189.3 ± 39.7	32.5 ± 5.65
↓ from baseline, %	-0.06 ± 0.24	-0.15 ± 0.47	0.03 ± 0.12
Significance from zero	0.12	0.032	0.075

Abbreviation: SD, standard deviation.

^aFemale 39 (52%) and male 36 (48%).

^bCHO (48.7%) and fat (32.2%).

Table 4. Comparison of Patients' Pre-/Postresults With 2 Similar Studies and the Academy of Nutrition and Dietetics EBNPGs Target Goal at Baseline and at 12 Months^a

Clinical Indicators	Timeframe	$\begin{array}{c} Lebanon \\ n=71^b \end{array}$	Comparison to a Study in Turkey ¹⁷ n = 68	Comparison to a Study in the United States ¹⁸ $n = 221$
Glycemic control $\mathrm{HbA_{IC}},\%$ Baseline and 12-mo findings ^c	Baseline 12 mo	9.1 ± 2.3 7.4 ± 1.3	7.7 ± 2.1 6.2 ± 0.9	8.7 ± 2.0
Change from baseline to follow-up at ^d	3 mo 6 mo 12 mo	$-1.1 \pm 1.8^{e,f}$ -1.8 ± 2.5^{e} -1.7 ± 2.5^{e}	-1.4 ± 1.7^{c} -1.5 ± 1.9^{c}	$-1.4 \pm 2.1^{\rm c}$ $-1.7 \pm 2.0^{\rm c}$
Percentage of patients at goal for HbA _{1C} , % < 6% to < 7% Parient profile data BMI. kg/m²	Baseline 12 mo	15.5% 38.0% ^h	50.8% 83.8%	
Baseline and 12-mofindings	Baseline 12 mo	31.7 ± 4.9 30.6 ± 4.9	29.9 ± 5.9 28.9 ± 5.2	34.6 ± 6.2
Change from baseline to follow-up at	3 mo 6 mo 12 mo	-0.7 ± 1.2^{c} -0.9 ± 2.2^{c} -1.1 ± 2.7^{c}	$-0.7 \pm 1.4^{\rm c}$ $-0.9 \pm 1.8^{\rm h}$	$-0.78 \pm 1.68^{\circ}$ $-0.94 \pm 2.30^{\circ}$
Percentage of patients at goal for BMI, $kg/m^{28} > 25$ than $5\%-10\%$ decrease Libid profile	Baseline 12 mo	12.3% 13.7%	26.5% 29.4%	
LDL, mg/dL Baseline and 12-mo findings	Baseline 12 mo	124.7 ± 45.5 107.3 ± 33.1	117.9 ± 40.1 116.5 ± 38.5	119.9 ± 37.0
Change from baseline to follow-up at	3 mo 6 mo 12 mo	-7.3 ± 23.3^{c} -14.0 ± 33.7^{c} -17.4 ± 31.4^{c}	$-8.7 \pm 32.6^{\text{h}}$ -0.9 ± 39.5	-2.3 ± 42.6 -8.9 ± 36.8
Percent of patients at goal for LDL < 100 mg/d ^g	Baseline 12 mo	30.0% 50.7% ^h	34.3% 27.9%	(continues)

 Table 4. Comparison of Patients' Pre-/Postresults With 2 Similar Studies and the Academy of Nutrition and Dietetics EBNPGs Target Goal
 at Baseline and at 12 Months^a (Continued)

Clinical Indicators	Timeframe	$\begin{array}{c} \textbf{Lebanon} \\ \mathbf{n} = 71^{\mathbf{b}} \end{array}$	to a Study in Turkey ¹⁷ $n = 68$	Study in the United States ¹⁸ $n = 221$
HDI, mg/dI Baseline and 12-mo findings	Baseline	453+106	46.4 + 11.4	43.7 + 12.4
	12 mo	47.8 ± 12.9	49.1 ± 11.8	i i
Change from baseline to follow-up at	3 mo	\uparrow 1.5 \pm 4.7 ^h	$\uparrow 2.9 \pm 16.9^{\rm i}$	$\uparrow 0.8 \pm 6.6$
	6 mo	$+3.1 \pm 7.0^{\circ}$	7 0 1 0 0	\uparrow 2.3 \pm 9.8
Percentage of patients at goal for HDI	12 mo Baseline	7.2.3 ± 8.0° 42.0%	7.5.9 ⊞ &. /- 47.8%	
>45 mg/dL ⁸ TG. mg/dL	12 mo	$55.1\%^{i}$	54.4%	
Baseline and 12-mo findings	Baseline	220.9 ± 223.1	197.3 ± 109.6	357.1 ± 601.6
	12 mo	166.4 ± 92.1	148.1 ± 77.8	
Change from baseline to follow-up at	3 mo	$-40.6 \pm 218.9^{\mathrm{e}}$	$-46.6 \pm 70.4^{ m e}$	-284.4 ± 840.8
	6 mo	-51.4 ± 222.1^{e}		-153.3 ± 660.1
	12 mo	$-45.4 \pm 232.6^{\mathrm{c}}$	$-48.6 \pm 75.0^{\mathrm{c}}$	
Percentage of patients at goal for TG	Baseline	36.1%	34.3%	
$< 150 mg/dL^g$	12 mo	$48.6\%^{i}$	57.4% ^h	
Blood pressure, mm Hg				
Systolic blood pressure, mm Hg				
Baseline and 12-mo findings	Baseline	131.3 ± 20.4	134.8 ± 22.3	127.0 ± 16.5
	12 mo	124.9 ± 9.9	124.1 ± 11.7	
Change from baseline to follow-up at	3 mo	$-5.7 \pm 15.3^{\rm e}$	$-9.2\pm18.7^{\rm e}$	$-3.8 \pm 15.2^{\rm h}$
	6 mo	$-6.9 \pm 16.7^{\mathrm{e}}$		$-5.4\pm16.6^{\mathrm{i}}$
	12 mo	$-6.4 \pm 16.6^{\mathrm{c}}$	$-10.7 \pm 20.1^{\rm c}$	
Diastolic blood pressure, mm Hg				
Baseline and 12-mo findings	Baseline	81.3 ± 12.5	82.4 ± 9.5	
	12 mo	78.1 ± 9.5	77.4 ± 6.6	
				(continues)

Table 4. Comparison of Patients' Pre-/Postresults With 2 Similar Studies and the Academy of Nutrition and Dietetics EBNPGs Target Goal at Baseline and at 12 Months^a (Continued)

Clinical Indicators	Timeframe	$\begin{array}{c} Lebanon \\ n=71^b \end{array}$	Comparison to a Study in Turkey ¹⁷ n = 68	Comparison to a Study in the United States ¹⁸ $n = 221$
Change from baseline to follow-up at Percentage of patients at goal for blood pressure < 130/80 mm Hg ⁸	3 mo 6 mo 12 mo Baseline 12 mo	$-2.5 \pm 9.6^{\circ}$ $-3.0 \pm 9.0^{\circ}$ $-3.1 \pm 9.3^{\circ}$ 60.0% $72.9\%^{\circ}$	-2.4 ± 17.1 $-5.0 \pm 9.9^{\circ}$ 61.8% $80.9\%^{\circ}$	

Abbreviations: BMI, body mass index; HbA₁c, glycosylated hemoglobin; HDI, high-density lipoprotein; LDI, low-density lipoprotein; TH, triglyceride.

^aValues are presented as means \pm standard deviations, if not otherwise specified. The minus sign (–) signifies mean decrease from baseline at 3, 6, and 12 months.

The up arrow sign (\uparrow) signifies mean increase from baseline at 3, 6, and 12 months.

^bData were missing for 4 patients.

^cOverall sample mean.

^dMean of individual differences from baseline.

 $^{e}P < .0001.$

Signifies increase in the difference between test periods.

level <100 mg/dL; HDL-cholesterol level > 45 to > 55 mg/dL; systolic blood pressure <130 mm Hg; diastolic blood pressure <80 mm Hg; and blood pressure <130/80 mm ⁸Goals from the 2001 Academy of Nutrition and Dietetics EBNPGs for patients with T2DM: HbA_{1C} level of <6% to <7%; BMI > 25, then 5% to 10% decrease; LDL-cholesterol

Hg.

 $^{
m h}P < .01.$

 $^{1}P < .001$

from 124.7 and 220.9 mg/dL at baseline to 107.3 and 166.4 mg/dL at 12 months, respectively (P < .0001). Also, patients' mean level of HDL-cholesterol was significantly improved from 45.3 mg/dL at baseline to 47.8 mg/dL at 12 months (P < .0001). Mean baseline values of systolic (131.3 mm Hg) and diastolic blood pressure (81.3 mm Hg) were also significantly reduced to 124.9 and 78.1 mm Hg, respectively, at 12 months (P < .0001) (Table 4). Also, the mean value of BMI was significantly reduced from 31.7 kg/m² at baseline to 30.6 kg/m² at 12 months (P < .0001) (Table 4).

Comparison of patients' clinical outcomes with the outcome goals of the Academy of Nutrition and Dietetics EBNPGs

The percentages of patients who met outcomes goals identified in the Academy's EBNPGs for T2DM for HbA_{1C}, fasting blood lipid profile, and BMI were calculated at baseline, 6 months, and 12 months. There was a significant increase in the percentage of patients who met the EBNPGs expected target goals at the end of the study compared with baseline (Table 4). Notably, at 12 months, 38.0% of the patients met the expected goal for HbA_{1C} compared with 15.5% at baseline, and 50.7% met the target goal for LDLcholesterol compared with 30.0% at baseline (Table 4). Overall, results indicated significant improvement in the clinical outcomes from baseline values, as 16.4% of patients achieved the expected outcomes (percent reduction) for HbA_{1C}, LDL-cholesterol, and blood pressure at 12 months, compared with only 2.7% of patients who met these targets at baseline. Data were not collected in a way that could separate the impact of medications from the impact of nutrition and lifestyle changes on patient outcomes since these changes were part of the overall medical care.

Dietitians' subjective ratings of patients' therapeutic lifestyle changes

Figure 2 shows the dietitians' subjective ratings of their patients' responses to selected therapeutic lifestyle changes between the first

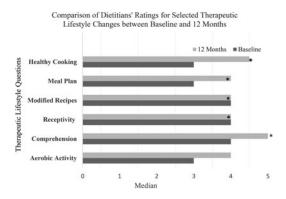


Figure 2. Dietitians' rating of participants' response to therapeutic lifestyle changes questions at baseline and 12 months using a Likert scale.

and last visits. Overall, dietitians rated the behavioral, therapeutic, and lifestyle changes showing some improvement during the study period. For example, dietitians' ratings of patients' responses to questions on healthy cooking, meal planning, modifying recipes, and patients' comprehension and receptivity to the Academy MNT protocol were significantly improved at 12 months compared with baseline ratings (P < .0001).

DISCUSSION

A rapid increase in the prevalence of T2DM in adults has occurred in Lebanon.^{4,7} Nutrition intervention is a cornerstone of diabetes management to achieve and maintain optimal glycemic and metabolic control and to improve overall health.^{6,20} Although implementation of the Academy EBNPGs for T2DM has been evaluated in the United States and other countries, 17,18 it was unclear whether using the same EBNPGs would yield similar outcomes because of variation in the sample population and the Lebanese health care system compared with the United States. Thus, the aim of the present study was to explore the outcome of implementing the Academy EBNPGs for diabetes in a sample of Lebanese patients newly diagnosed with T2DM. Overall, results of this pilot study suggest that patients who received nutritional care in accordance with EBNPG, as part of overall medical care, achieved significant improvements in clinical outcomes between baseline values and values at 3, 6, or 12 months. Notably, at 12 months, significant reductions (P < .0001) in the mean baseline values of HbA_{1C}, serum triglycerides, LDL-cholesterol, and BMI were noted. Also, at the 12 months, HDL-cholesterol level increased by 5.5% compared with baseline (P < .0001), and the mean baseline values of systolic and diastolic blood pressure were reduced by 4.9% and 3.9%, respectively.

Previous studies have also documented similar improvements in patients' glycemic control and metabolic outcomes following a nutrition intervention. 17-20 A study conducted by Franz et al¹⁹ among 179 American patients with type 2 diabetes reported a reduction in HbA_{1C} at 6 months compared with the baseline value (among 94 patients who had received a nutrition intervention), and results were used in the creation of the first 2001 Academy of Nutrition and Dietetics Guidelines for T2DM. Likewise, a study by Laitinen et al²¹ indicated that compliance with dietary recommendations, following 12 months of intensified nutrition education, led to a reduction in serum lipids in obese patients newly diagnosed with T2DM. Another study by Morrison et al²² conducted on 26 496 patients with T2DM found that more frequent visits with a primary care provider every 2 weeks were associated with faster reductions in HbA_{1C}, LDL-cholesterol, and blood pressure. In our study, the positive changes seen in patients' lifestyle and behavioral choices were maintained to the final visit at 12 months.

Although the improvements seen in our patients' glycemic control and metabolic outcomes may not be attributed solely to the implementation of the Academy EBNPGs, it is appropriate to conclude that patients achieved similar results when the EBNPGs were implemented in Lebanon, compared with the United States and a EBNPGs project in Turkey.^{17,18} In the United States, Lemon et al,¹⁸ who conducted a study among 221 patients newly diagnosed with T2DM using the Academy 2001 Nutrition Guidelines for

T2DM, reported a reduction in HbA_{1C} at 6 months postintervention. In a study conducted among 68 Turkish patients newly diagnosed with T2DM, improvement in patients' glycemic control and metabolic outcomes following implementation of the Academy EBNPGs was also documented.¹⁷

A comparison of our findings with those 2 earlier studies^{17,18} using the Academy EBNPGs is presented in Table 4. Results of our study are reported at baseline, 3, 6, and 12 months postintervention and include the percentage of patients who attained the expected target goal for the clinical outcome parameters. Overall, in these studies, patients' clinical outcome parameters (HbA_{1C}, LDL-C, HDL-C, triglyceride, blood pressure, and BMI) were significantly improved compared with baseline values. As an example, in our study, at 12 months, there was a reduction of 1.7% in HbA_{1C}, which is similar to the reduction of HbA_{1C} at 6 months reported by Lemon et al18 and the Turkish study group.17 The decrease in the HbA_{1C} seen in our study and the 2 other studies^{17,18} supports the idea that the use of the Academy EBNPGs in Lebanon. This finding may also show that the inclusion of dietitians as part of a patient care team can help patients adhere to the nutritional guidelines and achieve their HbA_{1C} targets.

Blood lipids and BMI values were also significantly improved in our patients at 12 months compared with baseline values. Lemon et al¹⁸ reported a reduction of 9.4% in the BMI and an increase of 2.3% in HDL-cholesterol. These figures were comparable to the results reported in our study at 6 months for BMI and HDL-cholesterol. However, the decrease in the LDL-cholesterol level (-12.8%) reported in our study at 6 months exceeded the figure that was reported by Lemon et al (-0.23%). This finding might be due to the improvement seen in our patients' healthy eating habits. Our dietitians reported improvement in patients' behavioral, therapeutic, and lifestyle changes regarding healthy cooking, meal planning, and modifying recipes during the study period (P < .0001) (Fig. 2). Also, at 12 months, comprehension and receptivity of patients to Academy MNT protocol were significantly improved (P < .0001) compared with baseline ratings. Although the lifestyle and behavioral ratings were subjective and based on the clinical judgment of dietitians during their interactions with their patients, they did reflect the improvement seen in patients' clinical outcomes. In fact, the efficacy of nutrition education and lifestyle counseling in diabetes management has been well established. $^{17-20,23}$

Results also indicated that patients improved their behavioral choices regarding healthy eating and physical activity and weight loss. Given the high rate of obesity among patients with diabetes in Lebanon, 4,6,7 weight loss is suggested for patients to improve their glycemic control and metabolic outcomes.^{6,7} In this study, at 12 months, patients' BMI was reduced by 3.5% from baseline. It has been found that modest weight loss in the range of 3% to 10% of body weight can result in reductions in blood glucose, serum lipid, and blood pressure. 24-28 Thus, encouraging patients to attend counseling and regular nutrition education sessions to manage their blood glucose and improve their metabolic outcomes is recommended for diabetes management.⁶ Moreover, the Look AHEAD study has already revealed that intensive behavioral lifestyle interventions were effective in promoting weight loss and reducing diabetes complications in overweight individuals with T2DM.24,29

Possible challenges to implementing the Academy EBNPGs protocol concerned issues with the amount of information included in the nutrition progress notes and patient education, the number and duration of counseling services provided to diabetic patients, and the differences from routine care in the health care system were noted by the dietitians. The dietitians thought that the nutrition progress note seemed to be lengthy and time consuming because they have limited time to see their patients at the clinic. Also, they tried to discuss all the checked items listed on the nutrition progress note at one visit, and found it overwhelming, even for a small number of patients. The dietitians also noted that patients' visits were longer than those usually scheduled and impacted their ability to accommodate the large number of patients who needed appointments. In Lebanon, patients usually have to pay for counseling services and testing devices, which was not the case in this study when nutrition care was free. In brief, using the Academy of Nutrition and Dietetics EBNPGs protocol for T2DM is feasible if the dietitians are provided with the proper training. Patients should also be provided with laboratory testing, nutrition consultations, and glucometers and testing strips to monitor their blood glucose free of charge. In the future, it is unclear whether dietitians or patients will be willing to devote the time and resources without the research support, despite the positive clinical outcomes achieved in this project.

Additional efforts should focus on exploring ways to provide education to all Lebanese dietitians on how to use the Academy of Nutrition and Dietetics EBNPGs protocol for diabetes, including the nutrition progress note as well as comparing guideline-based care with "usual care." This would help develop policies that support the adoption or adaptation of an evidence-based standardized practice nutrition guide for diabetes management in Lebanon.

Strengths and limitations

This pilot study was the first in Lebanon to evaluate the feasibility and outcomes of implementing the Academy nutrition guide for diabetes management in a sample of Lebanese patients who were newly diagnosed with T2DM. Our findings suggest that the Academy of Nutrition and Dietetics EBNPGs for T2DM, including nutrition therapy/counseling/nutrition education, can achieve the expected clinical outcomes for HbA_{1c} and LDL-cholesterol. Results showed that clinical outcomes were improved between baseline and as early as 3 months (at the second visit). Specifically, using the Academy EBNPGs, as part of patients' medical care, resulted in significant improvement in patients' HbA1C, LDL-cholesterol, HDLcholesterol, blood pressure, and weight status. The strength of this pilot study is that all of the dietitians received 2 weeks of face-to-face training on how to implement the Academy of Nutrition and Dietetics EBNPGs protocol. Also, this pilot showed that data collection to document patient outcomes can be part of routine nutrition care. Since this research was completed, newer EBNPG guidelines and toolkits are available for testing. 30-32 Thus, further research documenting the added value of using the newer EBNPGs is recommended.

The main limitation of this pilot study was the small sample size, which limits the generalization of this study's findings to all Lebanese patients. Also, the design of this study was a prospective, noncontrolled outcomes monitoring study, not an intervention study that compared guideline-based care with usual care. Accordingly, this study did not have a control arm to demonstrate a direct influence of using the Academy of Nutrition and Dietetics EBNPGs on outcomes. However, repeated measurement of patients' outcome parameters over time (3, 6, and 12 months) set the stage for future research. It should be designed to compare usual care directly to a designed intervention that can then support causal inferences and evidence whether implementing the EBNPGs improves patient clinical outcomes over patient outcomes from usual care. Given the serious implications of diabetes on health, research on this topic deserves further attention.

CONCLUSION

Implementing the Academy of Nutrition and Dietetics EBNPGs in counseling sessions provided by registered dietitians to Lebanese patients newly diagnosed with T2DM, as part of their medical care, over a 12-month period resulted in significant improvement in patient's clinical outcomes of HbA_{1C}, serum triglycerides, LDL-cholesterol, HDL-cholesterol, blood pressure, and BMI consistent with 38% to 50% meeting expected target goals identified in the EBNPGs for HbA_{1c} and LDL-cholesterol. Despite patients achieving positive clinical outcomes and dietitians being able to accommodate the EBNPG recommendations in this research, it is unclear whether providing care consistent with the Academy EBNPGs can be continued without further research, documenting the added value of using the EBNPGs. Future research is needed to compare clinical outcomes from EBNPG-driven nutrition therapy with usual care or medical care without dietitian involvement and to identify factors that can lead to a higher percentage of patients meeting expected outcomes identified in the EBNPG and/or research that can identify more clearly the contribution of nutrition care when considering the impact of all other aspects of medical care for newly diagnosed T2DM.

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