

Effects of the Dietary Approaches to Stop Hypertension (DASH) Eating Plan on Cardiovascular Risks Among Type 2 Diabetic Patients

A randomized crossover clinical trial

LEILA AZADBAKHT, PHD^{1,2}
NAFISEH RASHIDI POUR FARD, BSC³
MAJID KARIMI, MD³
MOHAMMAD HASSAN BAGHAEI, PHD³

PAMELA J. SURKAN, PHD⁴
MAJID RAHIMI, MSC³
AHMAD ESMAILZADEH, PHD^{1,2}
WALTER C. WILLETT, MD, DRPH^{5,6}

OBJECTIVE — To determine the effects of the Dietary Approaches to Stop Hypertension (DASH) eating pattern on cardiometabolic risks in type 2 diabetic patients.

RESEARCH DESIGN AND METHODS — A randomized crossover clinical trial was undertaken in 31 type 2 diabetic patients. For 8 weeks, participants were randomly assigned to a control diet or the DASH eating pattern.

RESULTS — After following the DASH eating pattern, body weight ($P = 0.007$) and waist circumference ($P = 0.002$) reduced significantly. Fasting blood glucose levels and A1C decreased after adoption of the DASH diet (-29.4 ± 6.3 mg/dl; $P = 0.04$ and $-1.7 \pm 0.1\%$; $P = 0.04$, respectively). After the DASH diet, the mean change for HDL cholesterol levels was higher (4.3 ± 0.9 mg/dl; $P = 0.001$) and LDL cholesterol was reduced (-17.2 ± 3.5 mg/dl; $P = 0.02$). Additionally, DASH had beneficial effects on systolic (-13.6 ± 3.5 vs. -3.1 ± 2.7 mmHg; $P = 0.02$) and diastolic blood pressure (-9.5 ± 2.6 vs. -0.7 ± 3.3 mmHg; $P = 0.04$).

CONCLUSIONS — Among diabetic patients, the DASH diet had beneficial effects on cardiometabolic risks.

Diabetes Care 34:55–57, 2011

Cardiovascular complications are the most frequent problem among type 2 diabetic patients (1). Therefore, a therapeutic approach that can control cardiometabolic risks might have beneficial effects for diabetic patients (2).

Although the Dietary Approaches to Stop Hypertension (DASH) diet was originally developed to prevent or treat high blood pressure (2), it is now recommended as an ideal eating pattern for all adults (3).

Effects of the DASH eating pattern in patients with metabolic syndrome (4) and hypertension (5,6) and other populations (7,8) can be generalized to individuals with diabetes.

Therefore, we assessed how the DASH eating pattern affects cardiometabolic risks in type 2 diabetic patients.

RESEARCH DESIGN AND METHODS — We enrolled 44 patients diagnosed with type 2 diabetes at

the Shaheed Motahari Hospital of Fooladshahr, Isfahan, during 2009. On the basis of the sample size formula suggested for crossover trials (9) $n = [(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times S^2]/2\Delta^2$, we determined that 21 patients were needed for adequate power.

A diagnosis of type 2 diabetes was confirmed if a patient either had a fasting plasma glucose ≥ 126 mg/dl or was taking oral glucose lowering agents or insulin (10). Exclusion criteria included any secondary cause of hyperglycemia, use of estrogen therapy, untreated hypothyroidism, smoking, and kidney or liver diseases. Cardiovascular risks such as fasting blood glucose, A1C, weight, waist circumference, and lipid profiles were the primary outcomes. All participants provided informed written consent. This study was approved by the research council and ethics committee of the Isfahan University of Medical Sciences (registered in <http://www.clinicaltrials.gov>; ID number NCT01049321).

Study procedures

We used a randomized crossover design. After a run-in period of 3 weeks, patients were randomly assigned to a control diet or a DASH diet for 8 weeks. This was followed by a wash-out period of 4 weeks. The project dietitian enrolled participants and randomly allocated them to groups using random sequencing generated in SPSS at the end of the run-in period. Because this was a dietary intervention, patients were not blinded.

Diets

We prescribed two diets for each patient: the control diet and the DASH diet. The control diet included a macronutrient composition of 50–60% carbohydrates, 15–20% protein, <30% total fat, and <5% of caloric intake from simple sugars (11). This composition was more similar to the Iranian dietary pattern and dietary habits. The DASH

From the ¹Food Security Research Center, Isfahan University of Medical Sciences, Isfahan, Iran; the ²Department of Nutrition, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran; ³Shaheed Motahari Hospital, Fooladshahr, Isfahan, Iran; the ⁴Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland; the ⁵Department of Nutrition, Harvard School of Public Health, Boston, Massachusetts; and the ⁶Department of Epidemiology, Harvard School of Public Health, Boston, Massachusetts.

Corresponding author: Leila Azadbakht, azadbakht@hlth.mui.ac.ir.

Received 8 April 2010 and accepted 3 September 2010. Published ahead of print at <http://care.diabetesjournals.org> on 15 September 2010. DOI: 10.2337/dc10-0676. Clinical trial reg. no. NCT01049321, clinicaltrials.gov. © 2011 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. See <http://creativecommons.org/licenses/by-nc-nd/3.0/> for details.

The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked "advertisement" in accordance with 18 U.S.C. Section 1734 solely to indicate this fact.

diet was rich in fruits, vegetables, whole grains, low-fat dairy products, and low in saturated fat, total fat, cholesterol, refined grains, and sweets. The amount of sodium intake was 2,400 mg per day (3). Patient adherence was assessed in terms of attendance at monthly visits and through analysis of the 3-day food diaries.

Measurements

All measurements were taken according to standard protocols. The laboratory staff was blinded to the treatment status.

Statistical analysis

We used general linear models (paired Student *t* tests) to globally compare means of the all variables at the end of the two different diet periods and the mean change for each variable in the two groups. Statistical analyses were performed using SPSS for Windows version 13.0 (SPSS, Chicago, IL).

RESULTS — Of the 44 participants, 31 type 2 diabetic patients (13 male and 18 female) completed the entire crossover study (one patient was diagnosed with cancer and one with anemia, and eleven patients did not follow the study protocol).

Analysis of the 3-day diet self-report showed that calorie intake of two the groups was not significantly different (2,165 ± 29 vs. 2,189 ± 35 Kcal/day in the control and DASH diets, respectively; *P* = 0.62). The results were the same regarding the actual protein intake (15 vs. 16%) and total fat intake (28 vs. 29%) as well as the percentage of the carbohydrate intake (57 vs. 55%) in the control and DASH diet groups, respectively. These two diets were different in sodium content (2,310 vs. 2,996 mg/day in the control and DASH diets, respectively). The DASH diet had higher amount of calcium (1,299 vs. 912 mg/day), potassium (4,399 vs. 3,219 mg/day) and fiber (30 vs. 26 g/day). In the DASH eating pattern versus the control diet, the number of servings of fruit (5 vs. 3), vegetables (6.8 vs. 4), dairy (3 vs. 2), and whole grains (4.5 vs. 2.5) was higher.

Effects of the two diets on cardiometabolic risks are shown in Table 1, indicating a significant reduction in most risk factors from the DASH diet.

CONCLUSIONS — We found that the DASH-eating pattern had beneficial

Table 1—Means of the cardiometabolic variables among type 2 diabetic patients after consumption of the DASH or control diet

	Control diet*	DASH diet†	<i>P</i> ‡
<i>n</i>	31	31	
Weight (kg)			
Baseline	75.0 ± 1.7	73.4 ± 1.8	0.001
End of trial	72.9 ± 1.8	68.4 ± 1.7	0.001
Change	−2.0 ± 0.3	−5.0 ± 0.9	0.006
Waist circumference (cm)			
Baseline	104.6 ± 1.9	103.4 ± 2.0	0.01
End of trial	102.7 ± 2.0	96.6 ± 1.9	0.001
Change	−1.9 ± 0.4	−6.7 ± 1.2	0.002
SBP (mmHg)			
Baseline	137.4 ± 2.8	134.5 ± 3.8	0.39
End of trial	134.2 ± 3.1	120.8 ± 3.2	0.001
Change	−3.1 ± 2.7	−13.6 ± 3.5	0.02
DBP (mmHg)			
Baseline	81.9 ± 2.2	81.8 ± 1.7	0.95
End of trial	81.2 ± 2.9	72.2 ± 2.7	0.01
Change	−0.7 ± 3.3	−9.5 ± 2.6	0.04
FBG (mg/dl)			
Baseline	171.8 ± 10.9	160.9 ± 10.1	0.73
End of trial	159.0 ± 8.3	131.5 ± 7.3	0.003
Change	−12.8 ± 6.7	−29.4 ± 6.3	0.04
A1C (%)			
Baseline	7.9 ± 1.9	7.7 ± 1.9	0.19
End of trial	7.4 ± 1.7	6.1 ± 0.5	0.05
Change	−0.5 ± 0.02	−1.7 ± 0.1	0.04
TG (mg/dl)			
Baseline	189.7 ± 19.3	170.7 ± 12.4	0.17
End of trial	178.7 ± 18.4	185.1 ± 13.8	0.53
Change	−10.9 ± 6.8	−14.4 ± 10.7	0.79
HDL-C (mg/dl)			
Baseline	41.2 ± 1.0	41.2 ± 1.0	0.97
End of trial	42.5 ± 1.0	45.6 ± 1.1	0.001
Change	1.3 ± 0.7	4.3 ± 0.9	0.001
LDL-C (mg/dl)			
Baseline	114.7 ± 3.5	118.7 ± 3.6	0.23
End of trial	111.9 ± 4.1	101.5 ± 3.1	0.02
Change	−2.7 ± 4.8	−17.2 ± 3.5	0.02
Total cholesterol (mg/dl)			
Baseline	213.3 ± 6.0	214.9 ± 5.7	0.80
End of trial	205.0 ± 6.6	192.7 ± 4.6	0.03
Change	−8.3 ± 6.3	−22.1 ± 5.7	0.11

Data are means ± SE. *The control diet was a designed to control diabetes. The general recommendation for macronutrient composition of the diet was 50–60% carbohydrates; 15–20% protein and <30% total fat. The amount of simple sugar was less than 5% of calorie intake. †The DASH diet was rich in fruits, vegetables, whole grains, and low-fat dairy products, and low in saturated fat, total fat, cholesterol, refined grains, and sweets. The amount of sodium intake was 2,400 mg per day. ‡*P* values are for comparisons between the two diet periods (general linear model). DBP, diastolic blood pressure; FBG, fasting blood glucose; HDL-C, HDL cholesterol; LDL-C, LDL cholesterol; SBP, systolic blood pressure; TG, triglyceride.

effects on type 2 diabetic patients' cardiometabolic parameters.

The prescribed caloric intake of both diets was the same, but the calorie density of food in the DASH diet was lower than that in the control diet. A long-term-weight-loss trial over 18 months also indicated beneficial effects of using low-

calorie-dense diets for weight loss (12). Furthermore, the dairy content, which might be related to weight reduction (13), was higher in the DASH diet was higher than the control diet.

The DASH eating pattern also had a more beneficial impact on the patient's glycemic control. More fiber, phytoestro-

gen, and isoflavone intake due to higher fruit and vegetable consumption, along with more weight reduction might be responsible for these effects (4).

The present study suggests the DASH diet plan could reduce LDL and increase HDL cholesterol. Our previous research on patients with metabolic syndrome also indicates a beneficial effect of this type of diet on lipid profiles (4). There was no difference in the serum triglyceride levels when we compared the effects of the two diets. However, DASH was compared with the control diet, which also had beneficial effects on lowering the serum triglyceride level.

Higher intake of legumes such as soy in the DASH diet might also be responsible for its beneficial effects on metabolic parameters (14). The kind of fat consumption in different diets is also important. Consuming higher amounts of nonhydrogenated vegetable oil with the DASH diet might be related to its more favorable effects.

Because nonadherent participants did not participate in all phases of the study, we could not use intention-to-treat analysis. Dietary intake in the present study was self-reported, and patients were given recommendations to follow a particular diet (rather than receiving prepared foods), likely resulting in possible imperfect adherence to the diets. The OmniHeart (Optimal Macro-nutrient Intake Heart) study (15) has expanded the macronutrient variability of the DASH dietary pattern, which will be interesting to explore in future studies.

The DASH eating pattern may play an important role in managing cardiometabolic risks among type 2 diabetic patients. Longer-term studies are needed to assess the sustainability of these effects.

Acknowledgments—This study was supported by the Isfahan University of Medical Sciences (primary sponsor). The facilities for conducting the biochemical experiments and sample recruitment were provided by Shahid Motahari Hospital of Fooladshahr, Isfahan Steel Company, Isfahan. All participants re-

ceived health insurance from the Isfahan Steel Company and attended the Shaheed Motahari Hospital of Fooladshahr.

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

L.A. and A.E. conceptualized and designed the study, performed statistical analyses, drafted the manuscript, and interpreted data. N.R.P.F. participated in data collection and entry and prescribed diets to the participants. M.K., M.H.B., and M.R. participated in data collection and took measurements. P.J.S. helped draft the manuscript and edited the English version of the manuscript. W.C.W. helped draft the manuscript and provided comments contributing to the interpretation of results. All authors approved the final manuscript for submission.

The authors thank the participants of the study for their enthusiastic support.

References

1. Kalofoutis C, Piperi C, Kalofoutis A, Harris F, Phoenix D, Singh J. Type II diabetes mellitus and cardiovascular risk factors: current therapeutic approaches. *Exp Clin Cardiol* 2007;12:17–28.
2. Vollmer WM, Sacks FM, Ard J, Appel LJ, Bray GA, Simons-Morton DG, Conlin PR, Svetkey LP, Erlinger TP, Moore TJ, Karanja N, DASH-Sodium Trial Collaborative Research Group. Effects of diet and sodium intake on blood pressure: subgroup analysis of the DASH-sodium trial. *Ann Intern Med* 2001;135:1019–1028.
3. Buse JB, Ginsberg HN, Bakris GL, Clark NG, Costa F, Eckel R, Fonseca V, Gerstein HC, Grundy S, Nesto RW, Pignone MP, Plutzky J, Porte D, Redberg R, Stitzel KF, Stone NJ, American Heart Association, American Diabetes Association. Primary prevention of cardiovascular diseases in people with diabetes mellitus: a scientific statement from the American Heart Association and the American Diabetes Association. *Circulation* 2007;115:114–126.
4. Azadbakht L, Mirmiran P, Esmailzadeh A, Azizi T, Azizi F. Beneficial effects of a Dietary Approaches to Stop Hypertension eating plan on features of the metabolic syndrome. *Diabetes Care* 2005;28:2823–2831.
5. Forman JP, Stampfer MJ, Curhan GC. Diet and lifestyle risk factors associated with incident hypertension in women. *JAMA* 2009;302:401–411.
6. Toledo E, de A Carmona-Torre F, Alonso A, Puchau B, Zulet MA, Martinez JA, Martinez-Gonzalez MA. Hypothesis-oriented food patterns and incidence of hypertension: 6-year follow-up of the SUN (Seguimiento Universidad de Navarra) prospective cohort. *Public Health Nutr* 2010;13:338–349.
7. Levitan EB, Wolk A, Mittleman MA. Consistency with the DASH diet and incidence of heart failure. *Arch Intern Med* 2009;169:851–857.
8. Liese AD, Nichols M, Sun X, D'Agostino RB Jr, Haffner SM. Adherence to the DASH Diet is inversely associated with incidence of type 2 diabetes: the insulin resistance atherosclerosis study. *Diabetes Care* 2009;32:1434–1436.
9. Fleiss JL. *The Design and Analysis of Clinical Experiments*. London, John Wiley and Sons, 1986, p. 263–271.
10. Harris TJ, Cook DG, Wicks PD, Cappuccio FP. Impact of the new American Diabetes Association and World Health Organisation diagnostic criteria for diabetes on subjects from three ethnic groups living in the UK. *Nutr Metab Cardiovasc Dis* 2000;10:305–309.
11. Anderson JW. Diabetes mellitus: medical nutrition therapy. In *Modern Nutrition in Health and Disease*. 10th ed. Shils ME, Shike M, Ross AC, Caballero B, Cousins RJ, Eds. Philadelphia, Lippincott Williams and Wilkins, 2006, p. 1051–1053.
12. Flood A, Mitchell N, Jaeb M, Finch EA, Laqua PS, Welsh EM, Hotop A, Langer SL, Levy RL, Jeffery RW. Energy density and weight change in a long-term weight-loss trial. *Int J Behav Nutr Phys Act* 2009;6:57.
13. Zemel MB, Thompson W, Milstead A, Morris K, Campbell P. Calcium and dairy acceleration of weight and fat loss during energy restriction in obese adults. *Obes Res* 2004;12:582–590.
14. Azadbakht L, Atabak S, Esmailzadeh A. Soy protein intake, cardiorenal indices, and C-reactive protein in type 2 diabetes with nephropathy: a longitudinal randomized clinical trial. *Diabetes Care* 2008;31:648–654.
15. Appel LJ, Sacks FM, Carey VJ, Obarzanek E, Swain JF, Miller ER 3rd, Conlin PR, Erlinger TP, Rosner BA, Laranjo NM, Charleston J, McCarron P, Bishop LM, OmniHeart Collaborative Research Group. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. *JAMA* 2005;294:2455–2464.