Effect of Legumes as Part of a Low Glycemic Index Diet on Glycemic Control and Cardiovascular Risk Factors in Type 2 Diabetes Mellitus

A Randomized Controlled Trial

David J. A. Jenkins, MD, PhD; Cyril W. C. Kendall, PhD; Livia S. A. Augustin, PhD; Sandra Mitchell, RD; Sandhya Sahye-Pudaruth, RD; Sonia Blanco Mejia, MD; Laura Chiavaroli, MSc; Arash Mirrahimi, MSc; Christopher Ireland, BSc; Balachandran Bashyam, PhD; Edward Vidgen, BSc; Russell J. de Souza, ScD; John L. Sievenpiper, MD; Judy Coveney, RD; Lawrence A. Leiter, MD; Robert G. Josse, MD

Background: Legumes, including beans, chickpeas, and lentils, are among the lowest glycemic index (GI) foods and have been recommended in national diabetes mellitus (DM) guidelines. Yet, to our knowledge, they have never been used specifically to lower the GI of the diet. We have therefore undertaken a study of low-GI foods in type 2 DM with a focus on legumes in the intervention.

Methods: A total of 121 participants with type 2 DM were randomized to either a low-GI legume diet that encouraged participants to increase legume intake by at least 1 cup per day, or to increase insoluble fiber by consumption of whole wheat products, for 3 months. The primary outcome was change in hemoglobin A1c (HbA1c) values with calculated coronary heart disease (CHD) risk score as a secondary outcome.

Results: The low-GI legume diet reduced HbA1c values by −0.5% (95% CI, −0.6% to −0.4%) and the high wheat fiber diet reduced HbA1c values by −0.3% (95% CI, −0.4% to −0.2%). The relative reduction in HbA1c values after the low-GI legume diet was greater than after the high wheat fiber diet by −0.2% (95% CI, −0.3% to −0.1%; P < .001). The respective CHD risk reduction on the low-GI legume diet was −0.8% (95% CI, −1.4% to −0.3%; P = .003), largely owing to a greater relative reduction in systolic blood pressure on the low-GI legume diet compared with the high wheat fiber diet (−4.5 mm Hg; 95% CI, −7.0 to −2.1 mm Hg; P < .001).

Conclusion: Incorporation of legumes as part of a low-GI diet improved both glycemic control and reduced calculated CHD risk score in type 2 DM.

Trial Registration: clinicaltrials.gov Identifier: NCT01063361


Lowe Glycemic Index (GI) foods have been shown to improve glycemic control in patients with type 2 diabetes mellitus (DM).1,2 Legumes, also known as pulses (dried beans, chickpeas, and lentils), were the first class of foods recognized as having low GI values3 and have been recommended in many national DM guidelines.4-6 However, few studies have assessed the effect of legumes in DM,7 even fewer have documented the quantity used to improve glycemic control, and none have reported their effect on cardiovascular risk.8 Not only are legumes good sources of slowly digested starch, but they are also relatively high in fiber and vegetable protein. Both fiber, notably viscous fiber, and also vegetable protein, specifically legume protein containing the 7S globulin fraction, are known to lower serum cholesterol levels.9-12 Furthermore, increased intakes of fiber9 and substitution of vegetable for animal proteins, as occur with increased legume consumption, have been associated with reductions in blood pressure (BP).13 In this respect, consumption of legumes, especially in the context of hypocaloric diets, also resulted in lower BP in patients without DM.14-17

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Author Affiliations are listed at the end of this article.
evant at a time when pharmacologic approaches to achieve improved glycemic control have not resulted in improved cardiovascular outcomes in the short term.18

We have therefore tested the effect on glycemic control, serum lipid levels, and BP of emphasizing increased legume intake as part of a low-GI diet in the treatment of type 2 DM.

METHODS

PARTICIPANTS

Participants were recruited from newspaper and public transport advertisements as well as hospital clinics. A total of 121 participants were eligible and randomized (Figure). Recruitment took place from February 16, 2010, to May 11, 2011, with the last study visit on August 8, 2011. Eligible participants had been diagnosed as having type 2 DM for at least 6 months, were taking a stable dose of oral antihyperglycemic agents for at least 1 month, and had hemoglobin A1C (HbA1C) values that were 5.5% to 8.5% of total hemoglobin both at initial screening and at the visit 1 week prior to commencing the study (Figure). (To convert HbA1C to a proportion of total hemoglobin, multiply by 0.01.) No participants had clinically significant cardiovascular, renal (creatinine level >1.70 mg/dL [>150 μmol/L]) or liver disease (alanine aminotransferase level >3 times the upper limit of normal [10-40 U/L, or 0.17-0.68 μkat/L]) or a history of cancer (Table 1).

PROTOCOL

The study followed a randomized, parallel design with 2 treatment arms of 3 months’ duration consisting of (1) a low-GI diet emphasizing legume consumption and (2) a high wheat fiber diet emphasizing high wheat fiber foods. After stratification by sex and HbA1C value (HbA1C value ≤7.1% of total hemoglobin), participants were randomized by a statistician (E.V.) who was geographically separate from the study center. Neither the dietitians nor the participants could be blinded, but equal emphasis was placed on the potential importance for health of both diets. The analytical technicians were blinded to treatment as, was the statistician, up to analysis of the primary outcome.

Participants attended the research center for screening and at week −1, baseline (week 0), and weeks 2, 4, 8, 10, and 12 of the study. At each visit, they were weighed, waist circumference was measured at the level of the umbilicus when standing, and a fasting blood sample was taken. Seated BP was measured in triplicate with an automatic sphygmomanometer (model

| Table 1. Baseline Characteristics of Study Participants |
|---------------------------------|-----------------|-----------------|
| Characteristic                  | Participants, No. (%) |
|                                | High Wheat Fiber Diet (n = 61) | Low-GI Legume Diet (n = 60) |
| Age, mean ± SEM, y              | 61 (1.0) | 58 (1.3) |
| Sex                             | 29 (48)  | 32 (53) |
| Men                             | 32 (52)  | 28 (47) |
| Women                           | 30 (49)  | 24 (40) |
| Race/ethnicity                  |            |            |
| European                        | 17 (28)   | 14 (23)  |
| East Indian                     | 18 (30)   | 16 (27)  |
| African                         | 10 (9)    | 6 (10)   |
| Other whites/white              | 5 (6)     | 10 (17)  |
| Others                          | 6 (10)    | 8 (13)   |
| Weight, mean ± SEM, kg          | 82.5 (2.2) | 85.6 (2.6) |
| BMI, mean ± SEM                 | 29.9 (0.7) | 31.4 (0.9) |
| Current smokers                 | 1 (1.6)   | 0       |
| HbA1C value, % of total hemoglobin, mean ± SEM | 7.2 (0.1) | 7.4 (0.1) |
| ≤7.1%                           | 30 (49)   | 24 (40)  |
| >7.1%                           | 31 (51)   | 36 (60)  |
| Duration of DM, mean ± SEM, y   | 8.6 (0.8) | 9.2 (0.8) |
| Medication use                  |            |            |
| Antihyperglycemic medications   | 61 (100)  | 60 (100) |
| Metformin                       | 50 (88)   | 56 (93)  |
| Sulfonylurea                    | 9 (15)    | 7 (12)   |
| Thiazolidinedione               | 5 (9)     | 7 (12)   |
| DPP-4 inhibitor                 | 7 (12)    | 6 (10)   |
| Meglitinides (nonsulfonylurea)  | 3 (5)     | 3 (5)    |
| α-Glucosidase inhibitors        | 0         | 2 (3)    |
| Cholesterol-lowering medications| 6 (10)    | 10 (17)  |
| Blood pressure medications      | 37 (61)   | 43 (72)  |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); DM, diabetes mellitus; DPP-4, dipeptidyl peptidase-4; GI, glycemic index; HbA1C, hemoglobin A1C.

SI conversion factor: To convert HbA1C to a proportion of total hemoglobin, multiply by 0.01.

*No significant differences in baseline characteristics were seen between treatments.
Participants.

Ontario, Canada, and written consent was obtained from all participants.

The low-density lipoprotein cholesterol (LDL-C) level and high-density lipoprotein cholesterol (HDL-C) levels. A coefficient of variation of 1.6% to 2.3% for blood glucose levels were also measured in the hospital routine analytical laboratory using a Random Access Analyzer and Beckman Coulter reagents (SYNCHRON LX Systems; Beckman Coulter), with laboratories. 

{LDL-C level = total cholesterol – [(triglycerides/5) / H11003

Energy requirements were calculated for each participant using the Harris-Benedict equation with allowance for light physical activity (ie, light exercise 1-3 days per week).19,20

Dietary interventions

Participants were provided with a checklist of 15-g carbohydrate-portions of recommended foods and the quantities they were expected to consume daily (eTable 1 and eTable 2; http://www.archinternmed.com). The target legume consumption was 1 cup per day (approximately 190 g per day, or 2 servings per day) of cooked beans, chickpeas or lentils, while a high wheat fiber diet was achieved by consumption of whole wheat and whole grain carbohydrate foods (whole wheat breakfast cereals, breads, brown rice, etc). Adherence to the diet was asessed from 7-day food records at the week zero visit and the mean of the last 3 visits (weeks 8, 10, and 12); 109 participants provided complete dietary and blood data for the 3-month study, and 114 also provided at least 1 data point during the last month of the study and were therefore classified as completers (Figure). At the conclusion of the study, participants were contacted and asked to rate their gastrointestinal symptoms before and at the end of the study on a scale of 0 to 6, where 0 was none, 3 was moderate, and 6 was excessive. Forty-four participants in the low-GI legume diet arm and 46 in the high wheat fiber diet arm responded.

Energy requirements were calculated for each participant using the Harris-Benedict equation with allowance for light physical activity (ie, light exercise 1-3 days per week).19,20

Biochemical and dietary analyses

The HbA1c value was analyzed within 24 hours using whole blood collected in EDTA Vacutainer tubes (Vacutainer; Becton, Dickinson and Co) in the hospital routine analytical laboratory by a turbidometric inhibition latex immunosay (TINIA Roche Diagnostics) with a coefficient of variation between assays of 3% to 4%. Blood glucose and serum lipid levels were also measured in the hospital routine analytical laboratory using a Random Access Analyzer and Beckman Coulter reagents (SYNCHRON LX Systems; Beckman Coulter), with a coefficient of variation of 1.6% to 2.3% for blood glucose level and 1.3% to 3.0% for total cholesterol, triglycerides, and high-density lipoprotein cholesterol (HDL-C) levels. The low-density lipoprotein cholesterol (LDL-C) level was calculated by the method of Friedewald et al11

[LDL-C level = total cholesterol – [(triglycerides/5) × (HDL-C level)].

Diet records were analyzed using a computer program (ESHA Food Processor SQL, version 10.1.1) based on US Department of Agriculture data2 and international GI tables3 using the bread scale (for glucose scale, multiply values by 0.71)4 with additional GI measurements made on local foods (Glycemic Index Laboratories).

Statistical analyses

Results are expressed as means ± SEM or 95% confidence intervals (CIs). The absolute CHD risk score was calculated using the Framingham risk equation.25 Any patient who met inclusion criteria, including an HbA1c value of at least 6.5% of total hemoglobin at the week −1 visit, and provided week 0 measurements was included in the analysis (n = 121). The mean of weeks −1 and 0 time was taken as baseline, and weeks 8, 10 and 12 were selected as end of study to allow for stabilization of HbA1c values as the main outcome. Treatment differences in physical and biochemical measures were assessed using all available data, and a repeated measures mixed (random effects) model accounting for time of assessment (SAS statistical software, version 9.2; SAS Institute Inc). The response variable was change from baseline, with diet and week as the main fixed-effects and patient identification nested in diet. There was no adjustment for baseline. An additional term representing an autoregression covariance assumption was included in the model for body weight since a significant time trend was observed over the 12-week treatment (specifically, over the 8- to 12-week period).

Multiple imputation (taking the mean of 5 sets of randomly imputed values) was used for Table 2 and Table 3 to generate data for those who dropped out or had missing values. Two participants were randomized but did not start, provided no data, and were unaware of their randomization and hence were not included in the analysis (modified intention to treat), nor were 8 participants whose week −1 HbA1c values were lower than 6.5% of total hemoglobin. Differences in gastrointestinal symptom scores were assessed by 2 sample t tests and within-treatment changes for other variables were assessed by paired t test (2-tailed) using data derived by multiple imputation. Changes in medication use were assessed by the likelihood ratio χ² test.

Results

Fifty-six of 60 participants (93.3%) completed the low-GI legume diet arm (ie, provided ≥1 blood sample in the final month), compared with a similar proportion, 58 of 61 (95.1%) completing the high wheat fiber diet arm. Participants did not differ significantly in baseline blood lipids levels, BP, or anthropometry (Table 1).

Dietary variables at baseline were different between treatments for saturated and polyunsaturated fats, as a percentage of total energy, on the low-GI legume diet relative to variables on the high wheat fiber diet (1.0%; P = .03 and −0.8%; P = .03, respectively), although the clinical significance of these differences is doubtful. During the study, there were also many similarly small statistically significant changes in dietary variables following increased legume consumption (Table 2). The absolute GI reduction on the low-GI legume diet was −14 GI units (95% CI, −16 to −13; P < .001), and the relative GI reduction compared with the high wheat fiber diet was −18 GI units (95% CI, −20 to −16; P < .001).
Oral antihyperglycemic medication dosages increased in 2 participants (both receiving the high wheat fiber treatment) and decreased in 3 participants based on the participants' physicians' decision owing to decreased blood glucose levels (1 in the high wheat fiber diet arm and 2 in the low-GI legume diet arm). Changes in medication were not different between treatments (P = .85).

The mean HbA1c value fell by −0.5% absolute HbA1c value (95% CI for change, −0.6% to −0.4%; P = .001) on the low-GI legume diet and by −0.3% absolute HbA1c value (95% CI, −0.4% to −0.2%; P < .001) on the high wheat fiber diet (Table 3). The relative HbA1c reduction on the low-GI legume diet was −0.2% of total hemoglobin (95% CI, −0.3% to −0.1%; P < .001) (Table 3) and remained significant after adjustment for body weight change (P = .005). Significant reductions in body weight were also seen on both the low-GI legume and high wheat fiber diets (−2.7 kg; 95% CI, −3.5 to −1.9 kg; and −2.0 kg; 95% CI, −2.5 to −1.5 kg, respectively; P < .001 for both comparisons) (Table 3). The treatment difference in body weight was also significant (P = .002), together with a significant reduction in waist circumference on the low-GI legume diet compared with the high wheat fiber diet (−1.4 cm; 95% CI, −2.3 to −0.4 cm; P = .007).

**SERUM LIPID LEVELS**

Lipid-lowering medications were decreased in 4 participants (1 in the high wheat fiber diet arm, 3 in the low-GI legume diet arm) and increased in 1 participant in the high wheat fiber diet arm, with no significant treatment difference (P = .21).

The low-GI legume diet produced significant decreases in total cholesterol level (−8 mg/dL; 95% CI, −13 to −4 mg/dL; P < .001) and triglyceride levels (−22 mg/dL; 95% CI, −30 to −13 mg/dL; P < .001) with no significant change in HDL-C level (−2 mg/dL; 95% CI, −4 to 0 mg/dL; P = .19). Meanwhile, the high wheat fiber diet resulted in a significant increase in HDL-C level (2 mg/dL; 95% CI, 1 to 3 mg/dL; P = .004). (To convert total cholesterol and HDL-C levels to millimoles per liter, multiply by 0.0259; to convert triglyceride to millimoles per liter, multiply by 0.0113.)

The relative reduction in total cholesterol level (−8 mg/dL; 95% CI, −13 to −2 mg/dL; P = .005) was greater in the low-GI legume diet arm, as was the reduction in HDL-C level (−2 mg/dL; 95% CI, −3 to −1 mg/dL; P < .001) owing to the rise in HDL-C level in the high wheat fiber diet arm. No other lipid treatment differences were significant (Table 3).

**BP AND HEART RATE**

Both BP and heart rate were reduced on the low-GI legume diet relative to the high wheat fiber diet (systolic BP, −4.5 mm Hg; 95% CI, −7.0 to −2.1 mm Hg; P < .001; diastolic BP, −3.1 mm Hg; 95% CI, −5.0 to −1.6 mm Hg; P < .001); and heart rate (−3.1 beats per minute [bpm]; 95% CI, −4.7 to −1.5 bpm; P < .001) (Table 3).
Increased legume consumption as part of a low-GI diet lowered HbA1c values, BP, heart rate, and estimated absolute CHD risk. These data provide support for the use of legumes as a specific food option to lower the dietary GI in type 2 DM and for the recommendations to increase low-GI food consumption by many national diabetes associations.4-6

This is the first study, to our knowledge, to promote the use of legumes specifically as the major focus of a low-GI diet for the treatment of DM and to report the quantities of legumes consumed. A previous meta-analysis of studies that included legumes as part of low-GI or high fiber interventions in type 2 DM demonstrated a 0.48% reduction in HbA1c values,8 similar to the 0.5% reduction observed with the low-GI legume diet in the current study. The US Food and Drug Administration has proposed a reduction of 0.3% to 0.4% in HbA1c value as therapeutically meaningful.28 The 1% and 0.67% absolute reductions in HbA1c values in the UKPDS27 and ADVANCE28 studies, respectively, resulted in 37% and 21% reductions in microvascular complications.

Use of wheat fiber as a positive control may have minimized the treatment difference. It is true that the increase in fiber intake was modest, but the baseline was already high at 16.6 g per 1000 kcal. The high wheat fiber diet resulted in a significant 0.3% reduction in HbA1c values, a significant rise in HbA1c values, a significant rise in HDL-C levels, and reductions in body weight, waist circumference, fasting blood glucose and triglyceride levels, and CHD risk. These data are in line with the findings from cohort studies, which have observed strong associations between cereal fiber intake and reductions in DM incidence and cardiovascular events.26-31 However, it is difficult to explain the in-
crease in the HDL-C level. To our knowledge, an increased HDL-C level has not previously been associated with increased wheat fiber intake.32 Furthermore, the lack of association between change in the HDL-C level and legume consumption on the low-GI legume diet (r = −0.02; n = 56; P = .86) does not support an effect of beans in lowering the HDL-C level.

To our knowledge, this trial is the first to demonstrate a BP reduction with legume consumption in type 2 DM. This reduction was all the more remarkable since the mean starting BP was already in the acceptable range at 122/72 mmHg. Increased plant food and plant protein consumption has been associated with lower BP, as seen with the DASH diet.33,34 Consumption of baked beans in an analysis of the NHANES data was associated with lower BP,35 and trials of bean-enriched diets, specifically the use of lupins, have also demonstrated a reduction in BP,14,15 although not all studies of bean consumption have shown this effect.17

The exact mechanisms for the BP reduction associated with bean intake are not known. Peptides digested from proteins, notably from casein (lactopeptides), may be absorbed and have antihypertensive effects.36 Other protein sources may also produce antihypertensive peptides.37 Beans specifically are good sources of potassium and magnesium, which may reduce BP38,39 and by virtue of their low GI are likely to result in lower postprandial insulin levels, associated with reduced salt retention and lower BP.40,41 Acarbose, which converts dietary carbohydrates into a slow-release, low-GI form, has also been associated with a reduced incidence of hypertension and CHD events in prediabetic participants in the STOP NIDDM trial.42 In addition to the potential direct beneficial effects of vegetable protein and fiber, there is also the potential displacement value of vegetable protein foods in reducing animal protein foods, which are higher in saturated fat and cholesterol, as has been shown for increased soy consumption.33

To our knowledge, this study is also the first to assess the effect of bean consumption on heart rate and indeed one of the few to determine the effect of any dietary intervention. Previous studies have suggested that increased heart rate is associated with increased CHD risk.35 Relatively little work has been done recently with this simple measurement to define the dose-response relation of heart rate to CHD risk; however, earlier studies suggest a doubling of CHD risk for every increase of 10 bpm.44

The study weaknesses include the relatively small changes observed in glycemic control, blood lipid levels, and BP compared with the control arm. However, the use of an effective control diet (positive control) may have minimized the opportunity to see treatment differences. Furthermore, this study was ad libitum in nature, with self-reported diet records and likely underreporting of food intake, as evidenced by the relatively low caloric intakes.

These findings linking legume consumption to both improved glycemic control and reduced CHD risk are particularly important because type 2 DM is increasing most rapidly in the urban environments of populations in which bean intake has traditionally been high (eg, India, Latin America, the Pima Indians of Arizona).45,46 Support for the continued use of such foods in traditional bean-eating communities, together with their reintroduction into the Western diet, could therefore be justified even if the effect on glycemia is relatively small, given the magnitude of the problem and the need for acceptable dietary options, especially those options that may also have a BP and cardiovascular advantage.

In conclusion, legume consumption of approximately 190 g per day (1 cup) seems to contribute usefully to a low-GI diet and reduce CHD risk through a reduction in BP. This effect of legumes seems analogous to that seen with acarbose, which also transforms the dietary carbohydrate into a more slowly digested low-GI form and has been associated with a reduced rate of hypertension and CHD events in prediabetic individuals.42

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Author Affiliations: Clinical Nutrition and Risk Factor Modification Center (Drs Jenkins, Kendall, Augustin, Blanco Mejia, Bashyam, de Souza, and Sievenpiper, Mss Mitchell, Sahye-Pudaruth, Chiavaroli, and Covenev), Division of Endocrinology and Metabolism (Drs Leiter and Josse), Keenan Research Center of the Li Ka Shing Knowledge Institute (Drs Jenkins, Leiter, and Josse), St Michael’s Hospital, Toronto, Ontario, Canada; Departments of Nutritional Sciences (Drs Jenkins, Kendall, Augustin, Blanco Mejia, Bashyam, Leiter, and Josse, Ms Chiavaroli, and Mr Mirrhami) and Medicine (Drs Jenkins, Leiter, and Josse), Faculty of Medicine, University of Toronto, Toronto; College of Pharmacy and Nutrition (Dr Kendall), University of Saskatchewan, Saskatoon, Saskatchewan, Canada; and Departments of Clinical Epidemiology and Biostatistics (Dr de Souza) and Pathology and Molecular Medicine (Dr Stevenpiper), Faculty of Health Sciences, McMaster University, Hamilton, Ontario.

Correspondence: David J. A. Jenkins, MD, PhD, Department of Nutritional Sciences, University of Toronto, 150 College St, Toronto, ON M5G 2M4, Canada (NutritionProject@smh.ca).

Author Contributions: Drs Jenkins, Kendall, and Augustin and Mr Vidgen had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Jenkins and Kendall. Acquisition of data: Augustin, Mitchell, Sahye-Pudaruth, Blanco Mejia, Chiavaroli, Mirrhami, Ireland, and Covenev. Analysis and interpretation of data: Jenkins, Kendall, Augustin, Bashyam, Vidgen, de Souza, Stevenpiper, Leiter, and Josse. Drafting of the manuscript: Jenkins and Kendall. Critical revision of the manuscript for important intellectual content: Jenkins, Kendall, Augustin, Mitchell, Sahye-Pudaruth, Blanco Mejia, Chiavaroli, Mirrhami, Ireland, Bashyam, Vidgen, de Souza, Stevenpiper, Leiter, Covenev, and Josse. Statistical analysis: Vidgen and de Souza. Obtained funding: Jenkins and Kendall. Administrative, technical, and material support: Kendall, Augustin, Chiavaroli, Mirrhami, Ireland, and Bashyam. Study supervision: Jenkins, Kendall, Augustin, Leiter, and Josse.

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**Online-Only Material:** The eTables are available at http://www.archinternmed.com.

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Diabetes Mellitus Nutrition Therapy

Beyond the Glycemic Index

The importance of the glycemic index (GI) and fiber in diabetes mellitus (DM) nutrition therapy has been controversial. In this issue of the Archives, Jenkins et al. compared a lower-GI (46%, glucose scale), high soluble fiber (fiber source primarily legumes; 37.6 g of fiber per day) diet with a higher-GI (58%, glucose scale), whole wheat fiber (26.8 g of fiber per day) diet. Both diets decreased hemoglobin A1c, −0.5% and −0.3%, respectively. Lipid values also improved from both diets, and systolic blood pressure decreased by −4.5 mm Hg on the lower-GI, high soluble fiber diet. Absolute coronary risk (10-year percentage) decreased from 10.7% to 9.6% and from 10.4% to 9.9%, respectively. Are the modest benefits from the dietary components, or are they a result of the reduced energy intake of approximately 200 kcal per day? The more important question might be whether people with DM can implement any of these often difficult interventions in the “real world” to the extent it will have an impact on their glycemic control or cardiovascular risk factors.

The role of the GI in DM nutrition therapy has been controversial for several reasons. First of all, the definition is confusing. The GI measures the relative area under the postprandial glucose curve of 50 g of digestible carbohydrates compared with 50 g of a standard food, either glucose or white bread. It does not measure how quickly foods are digested and absorbed into the blood stream as claimed by diet books (and many health pro-