

Reproducibility and validity of a quantitative FFQ designed for patients with type 2 diabetes mellitus from southern Brazil

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Abstract

Objective: To evaluate the reproducibility and validity of a previously constructed FFQ to assess the usual diet of patients with type 2 diabetes mellitus (T2DM).

Design: Cross-sectional survey using two quantitative FFQ (1-month interval) supported by a food photograph portfolio, a 3 d weighed diet record (WDR) and urinary N output measurement (as a biomarker of protein intake).

Setting: Group of Nutrition in Endocrinology, southern Brazil.

Subjects: Out-patients with T2DM.

Results: From a total of 104 eligible T2DM patients, eighty-eight were included in the evaluation of FFQ reproducibility and seventy-two provided data for the validity study. The intakes estimated from the two FFQ did not differ ($P > 0.05$) and the correlation coefficients were significant ($P < 0.01$) for energy and nutrients, ranging from 0.451 (soluble fibre) to 0.936 (PUFA). Regarding the validity evaluation, data from the FFQ were higher than those from the WDR for total (28.3%), soluble (27.4%) and insoluble fibres (29.1%), and SFA (13.5%), MUFA (11.1%) and total lipids (9.2%; all $P < 0.05$). There were significant correlation coefficients between the FFQ and WDR for most nutrients, when adjusted for energy intake and de-attenuated. Also, the Bland–Altman plots between the FFQ and WDR for energy and macronutrient intakes showed that the FFQ may be used as alternative method to the WDR. The validity coefficient (using the method of triads) for the FFQ protein intake was 0.522 (95% CI 0.414, 0.597).

Conclusions: This quantitative FFQ was valid and precise to assess the usual diet of patients with T2DM, according to its validity and reproducibility.

Keywords

Type 2 diabetes mellitus
FFQ
Food records
Nutritional epidemiology

The influence of diet in the development of human disease has been the central focus of nutritional epidemiology⁽¹⁾. There are several methods to evaluate food and nutrient consumption as well as energy intake, including 24 h recalls, diet records, FFQ⁽²⁾ and biomarkers⁽³⁾. Dietary assessment is often carried out to develop and implement nutritional advice, promote health, prevent illness and improve nutritional status⁽⁴⁾.

The management of patients with diabetes includes, besides pharmacological therapy, lifestyle changes^(5,6). The intensive control of hyperglycaemia and hypertension reduces or halts the development of diabetic chronic complications⁽⁶⁾. The best pharmacological strategy to lower glucose in patients with type 2 diabetes mellitus (T2DM) has been continuously evaluated⁽⁷⁾, but few

patients reach the suggested targets. In fact, only 24% of Brazilian diabetic patients had glycated Hb (HbA1c) lower than the recommended target (HbA1c < 7%)⁽⁸⁾. In this sense, lifestyle changes, especially dietary intervention, should be reinforced⁽⁶⁾. However, the relationship between diet and diabetes complications has not been completely elucidated.

To investigate the association between components of diet and the development of chronic diabetic complications, the dietary evaluation should cover a long period, months or years, as is the case of FFQ⁽¹⁾. The FFQ should be based in a specific population and its validity and reproducibility should always be tested⁽¹⁾. The validity is examined by comparing FFQ data with a reference method and/or biomarkers⁽⁹⁾. The weighed diet record

(WDR) has been considered the best dietary tool for the validation procedure⁽¹⁰⁾. Biomarkers evaluate specific nutrients, such as urinary urea-N for estimating protein intake⁽¹¹⁾. Finally, to evaluate the FFQ reproducibility, the dietary instrument should be tested at least on two separate occasions⁽¹²⁾.

To date, only four FFQ have been developed and validated for patients with diabetes in specific ethnic populations^(13–16). We recently constructed a Brazilian FFQ for diabetes⁽¹⁷⁾. Therefore, the present study aimed to evaluate the performance (validity and reproducibility) of this FFQ in the assessment of the usual diet of patients with T2DM by comparing it with a 3 d WDR and a biomarker of protein intake.

Experimental methods

Patients

The present study was conducted in patients with T2DM, defined as individuals over 30 years of age at onset of diabetes, with no previous episode of ketoacidosis or documented ketonuria, and with initiation of insulin therapy (when present) at least 5 years after diagnosis. The study recruited out-patients who consecutively attended the Endocrinology Division of the Hospital de Clínicas de Porto Alegre, Brazil and who had not previously been submitted to any dietary assessment.

The inclusion criteria were: age <80 years, serum creatinine <2.0 mg/dl and BMI <40.0 kg/m². Patients using corticosteroid drugs and with orthostatic hypotension or gastrointestinal symptoms suggestive of autonomic diabetic neuropathy were excluded. The study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving patients were approved by the Ethics Committee of the Hospital de Clínicas de Porto Alegre, Brazil. Written informed consent was obtained from all patients.

Patients were submitted to clinical, lifestyle and anthropometric evaluation. Information about clinical data (co-morbidities associated with diabetes and medication use) was collected from the patients' most recent medical records. Hypertension was defined as a mean of the measurement of systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg, the use of an antihypertensive drug or self-reported identification⁽¹⁸⁾. Patients were defined as microalbuminuric when the value of urinary albumin excretion (UAE) was 17–174 mg/l or UAE 30–299 mg/24 h or as macroalbuminuric when UAE ≥ 174 mg/l or UAE ≥ 300 mg/24 h. The diagnosis of micro- or macroalbuminuria was always confirmed⁽¹⁹⁾. Patients were classified as current smokers or not (former and non-smokers) and self-identified as white or non-white. Economic status was evaluated by a standardized Brazilian questionnaire⁽²⁰⁾ and physical activity level was classified according to the short version of the International

Physical Activity Questionnaire⁽²¹⁾ culturally adapted to the Brazilian population⁽²²⁾. Physical activity was graded into three levels: low, moderate and high, according to activities during a typical week⁽²¹⁾. The body weight and height of patients (light clothing and without shoes) were obtained with measurements recorded to the nearest 100 g for weight and to the nearest 0.1 cm for height. BMI (kg/m²) was then calculated. Waist circumference was measured at the midpoint between the iliac crest and the last floating rib. Also, hip circumference was measured at the largest circumference of the buttocks. A flexible and non-stretchable fibreglass tape was used for these measurements.

Dietary assessment

The patients' usual diet was assessed by the FFQ (study factor), a 3 d WDR (used as a relative reference) and a biomarker for protein intake (urinary urea-N output) from February 2010 to May 2011. The FFQ was constructed with dietary data from a sample of 188 out-patients with T2DM: 61.1 (SD 10.1) years old, 50.0% males, median of 12 (6–18) years of diabetes duration, BMI of 28.8 (SD 4.3) kg/m², HbA1c of 7.5 (SD 1.4)%, 42.5% from lower-middle class and 84.4% self-identified as white⁽¹⁷⁾. Briefly, dietary data from a 3 d WDR were used to construct a list of foods usually consumed. Portion sizes were determined according to the 25th, 50th, 75th and 95th percentiles of intake for each food item. A total of sixty-two food items were selected on the basis of the 3 d WDR, and another twenty-seven foods or their preparation options and nine beverages were included after expert examination. The frequency was described as the number of times the food was consumed and also if the intake occurred daily, weekly, monthly or yearly. Also, a portfolio with photographs of each included food item and its portion sizes was created to assist the patients in identifying the consumed portion. The final version of the FFQ consisted of ninety-eight most commonly consumed food items and covered the past 12 months⁽¹⁷⁾.

The FFQ was applied by a nutritionist (R.A.S.) in an interview, twice, with a 1-month interval. After this, the patients underwent a 3 d WDR (two non-consecutive weekdays and one day off at an interval of 3 weeks) as previously standardized⁽²³⁾. Compliance with the WDR technique was confirmed by comparison between the protein intake estimated from the 3 d WDR and from the 24 h urinary urea-N output⁽¹¹⁾. To be included in the validity evaluation of the FFQ, misreporting should be excluded. Misreporting was defined when the ratio of protein intake estimated from the WDR to protein intake estimated by urinary urea-N was <0.79 or >1.26⁽²⁴⁾. The protein intake estimated from urinary urea-N was also used as a biomarker to evaluate the agreement of protein intake from the FFQ with that from the 3 d WDR.

The food intakes reported in the dietary instruments (FFQ and 3 d WDR) were converted into daily intakes and

their nutritional composition was calculated with the software Nutribase Clinical[®] (CyberSoft Inc., Phoenix, AZ, USA) that is based on food composition data from the US Department of Agriculture⁽²⁵⁾. The amount of *trans*-fatty acids was derived from the *Tabela de Composição dos Alimentos – TACO*⁽²⁶⁾, the US Department of Agriculture⁽²⁷⁾, Slover *et al.*⁽²⁸⁾ and the TRANSFAIR Study⁽²⁹⁾. The total, soluble and insoluble dietary fibre contents were estimated from data available in the *CRC Handbook of Dietary Fiber in Human Nutrition*⁽³⁰⁾. The glycaemic index (GI) and glycaemic load (GL) were obtained from the international tables⁽³¹⁾. When the GI of foods present in the instruments was not found, we used data from food with a similar composition.

Laboratory evaluation

Blood samples were obtained after a 12 h fast. Plasma glucose was determined by the glucose oxidase method; serum and urinary creatinine level by Jaffe's reaction; HbA1c was tested by HPLC (Tosoh 2·2 Plus HbA1c; Tosoh Corporation, Tokyo, Japan; reference value: 4·8 to 6·0%); total cholesterol and TAG were measured by enzymatic colorimetric methods; and HDL-cholesterol was determined by the homogeneous direct method. LDL-cholesterol was calculated using the Friedewald formula: LDL-cholesterol = total cholesterol – HDL-cholesterol – (TAG/5)⁽³²⁾ only for patients with TAG values <400 mg/dl.

On the third day of the WDR, urea was measured in a 24 h urine collection. Collection of the 24 h urine started in the morning of the first day with the second morning urine and lasted until the second day, at the same hour, with the first morning urine. Completeness of urine collection was confirmed by 24 h creatinine measurements: 700 to 1500 mg/24 h for women and 1000 to 1800 mg/24 h for men⁽³³⁾. Protein intake was estimated from 24 h urinary urea-N output and calculated using Maroni's formula as follows: protein intake (g/d) = nitrogenated intake × 6·25; where nitrogenated intake = urinary urea-N (= urinary urea/2) + non-ureic N (= 0·031 g/kg current weight)⁽¹¹⁾. Urinary albumin excretion was measured by immunoturbidimetry (MicroAlb Sera-Pak[®] immunomicroalbuminuria; Bayer, Tarrytown, NY, USA) on a Cobas Mira Plus[®] (Roche, Indianapolis, IN, USA) and urinary urea was measured by an enzymatic UV method.

Statistical analysis

Results are expressed as mean and standard deviation or as median and interquartile range, and the Gaussian distribution was verified by the one-sample Kolmogorov–Smirnov test. Data were log-transformed before analyses to normalize distributions. All data analyses were performed using the statistical software package IBM SPSS Version 18·0 and the type I error rate was fixed at $P \leq 0\cdot05$ (two-tailed).

To evaluate the FFQ reproducibility, data from the first and second FFQ were compared by Student's *t* test or

Wilcoxon's *U* test for paired samples and Pearson correlation coefficients were calculated with crude data and data adjusted for energy intake according to the residual method⁽¹⁾.

In the validity study, data from the second FFQ, the 3 d WDR (relative reference) and the biomarker (for protein intake only) were evaluated, comparing these dietary tools using Student's *t* test or Wilcoxon's *U* test for paired samples, Pearson correlation coefficients, and their agreement by Bland–Altman plots⁽³⁴⁾. Pearson correlation coefficients were calculated using crude data and data adjusted for energy intake⁽¹⁾. Correlation values were corrected by the ratio of the intra- and inter-individual variances, obtained by analysis of the 3 d WDR, through the following equation: $r_d = r_o (1 + \lambda/n)^{1/2}$, where r_d is the de-attenuated correlation, r_o is the observed correlation between FFQ and WDR, λ is the intra- and inter-individual variance ratio in the WDR and n is the number of replicates, which comprised three food records⁽¹⁾. Further, the correlation between protein intake estimated from the FFQ and true protein intake was performed according to the method of triads, considering the protein intake estimated by the second FFQ and the 3 d WDR and the measured protein intake using urinary urea-N output as biomarker⁽³⁵⁾.

In the sample size calculation a minimum correlation coefficient of 0·40⁽¹⁾ between the protein intake estimates by FFQ and 3 d WDR, a type I error (two-tailed) of 5% and a type II error of 10% were taken into account. For the validity study, sixty-two patients were required; for the reproducibility evaluation, considering a 20% dropout, seventy-five patients needed to be studied.

Results

Patients

Out of a total of 104 participants eligible for the study, three patients (2·9%) refused to participate and thirteen patients (12·5%) agreed to participate but they did not return for another visit to answer the second FFQ. Furthermore, sixteen patients (15·4%) performed an unsatisfactory WDR and they were not included in the validity evaluation. We did not observe differences in characteristics between the patients included in the validity evaluation (n 72) as compared with these sixteen misreporting patients ($P > 0\cdot100$ for all analyses; data not shown). Therefore, eighty-eight patients were included for the reproducibility evaluation and seventy-two patients provided complete data for the validity study. The demographic, clinical, anthropometric and laboratory characteristics of the patients included in each study are shown in Table 1.

Reproducibility evaluation

The daily intake data obtained from the first and second FFQ were compared and are shown in Table 2. The reported intakes of energy, macronutrients, fibres, GI and

Table 1 Demographic, clinical, anthropometric and laboratory characteristics of Brazilian patients with type 2 diabetes mellitus included in the reproducibility and validity studies

Characteristic	Reproducibility study (n 88)		Validity study (n 72)	
	Mean or median	SD or IQR	Mean or median	SD or IQR
Female (%)		58.0		55.6
Age (years)	63.3	8.5	61.9	9.3
Diabetes duration (years)	10	3–17	10	3–17
White (%)		71.6		73.6
Hypertension (%)		89.8		87.5
Micro- or macroalbuminuria (%)		31.8		33.4
Diabetes treatment (%)				
Diet		2.3		2.8
Oral hypoglycaemic drugs		44.3		43.1
Insulin		8.0		9.7
Insulin and oral hypoglycaemic drugs		40.5		44.4
Economic status (%)				
Upper and upper-middle class		47.7		55.6
Middle class		46.6		38.9
Lower-middle and lower class		5.7		5.6
Current smoking (%)		6.8		5.6
Physical activity† (%)				
Low level		60.2		55.9
BMI (kg/m ²)	29.6	3.9	28.8	4.3
Waist circumference (cm)				
Male	102.9	10.7	102.3	10.7
Female	100.1	9.6	100.3	10.0
Hip circumference (cm)				
Male	103.3	7.1	103.3	7.4
Female	106.7	8.0	106.9	8.1
Fasting plasma glucose (mg/dl)	163.1	69.2	145.8	59.3
Total cholesterol (mg/dl)	177.5	36.9	183.1	45.9
HDL-C (mg/dl)				
Males	42.3	10.7	42.4	11.3
Females	47.3	12.5	46.6	13.3
LDL-C (mg/dl)	103.7	31.9	109.3	36.3
TAG (mg/dl)	131.0	95.0–180.0	119.0	94.0–178.0
HbA1c (%)	8.9	2.0	8.5	2.0
Serum creatinine (mg/dl)	0.9	0.2	0.8	0.2

IQR, interquartile range; HDL-C, HDL-cholesterol; LDL-C, LDL-cholesterol; HbA1c, glycated Hb.

Data are expressed as mean and standard deviation, or median and interquartile range, or proportion of patients with the analysed characteristic (%).

†None of the patients were identified as having a high level of physical activity.

Table 2 Energy, macronutrient and fibre intakes, glycaemic index and glycaemic load estimated from the two FFQ applied at an interval of 1 month in Brazilian patients with type 2 diabetes mellitus included in the reproducibility study (n 88)

Nutrient	First FFQ		Second FFQ		P value	Pearson correlation†	
	Mean or median	SD or IQR	Mean or median	SD or IQR		Crude data	Adjusted‡
Energy (kJ)	9225.7	3332.5	8944.9	3009.5	0.241§	0.725	–
Protein (g)	90.9	68.0–106.2	86.6	70.4–118.1	0.396	0.693	0.602
Carbohydrate (g)	264.7	212.6–308.3	244.5	198.6–295.2	0.121	0.595	0.520
Total fibre (g)	26.4	10.0	25.4	9.5	0.256§	0.563	0.505
Soluble fibre (g)	9.4	3.5	8.9	3.4	0.226§	0.534	0.471
Insoluble fibre (g)	17.0	6.8	16.2	6.5	0.238§	0.536	0.451
Total lipids (g)	81.5	33.6	80.3	25.6	0.582§	0.783	0.658
SFA (g)	24.2	13.4	24.0	9.8	0.802§	0.749	0.609
MUFA (g)	26.7	11.6	26.6	8.8	0.919§	0.725	0.634
PUFA (g)	21.4	9.0	21.5	8.2	0.680§	0.925	0.936
Trans-fatty acids	1.5	0.9–2.2	1.6	1.1–2.4	0.302	0.683	0.629
Glycaemic index (%)	56.5	5.5	55.9	4.6	0.142§	0.623	0.618
Glycaemic load (g)	125.7	96.7–167.5	120.7	93.5–142.2	0.112	0.633	0.561

IQR, interquartile range.

†The energy and nutrient values were log-transformed to normalize the distribution and calculate the correlation coefficients. All Pearson correlations are $P < 0.001$.

‡Data adjusted for energy intake according to the residual method⁽¹⁾.

§Student's *t* test for paired samples.

||Wilcoxon's *U* test for paired samples.

GL were not different between the two applications of the FFQ. The correlation coefficients between the nutrients reported in the first FFQ and second FFQ were calculated and are also shown in Table 2. All correlation coefficients were significant before and after the energy adjustment ($P < 0.05$ for all analyses). The PUFA values showed a strong correlation ($r = 0.936$) and most nutrients showed moderate correlation values: the highest value was for total lipids ($r = 0.658$) and the lowest was for insoluble fibre ($r = 0.451$).

Validity study

The data of daily intake from the second FFQ were compared with those from the mean of the 3 d WDR in the validity evaluation and are shown in Table 3. The mean values of nutrient intakes reported from the FFQ for total (28.3%), soluble (27.4%) and insoluble fibres (29.1%), SFA (13.5%), MUFA (11.1%) and total lipids (9.2%) were higher than corresponding values from the 3 d WDR ($P < 0.05$ for all comparisons). Only the GI values reported in the FFQ were 2.6% lower than in the 3 d WDR ($P = 0.041$).

Regarding correlations, de-attenuation improved the values for all dietary data and these results are also shown in Table 3. However, only soluble and insoluble fibres did not show significant correlations between FFQ and 3 d WDR values after energy adjustment. Total lipids ($r = 0.855$) and PUFA ($r = 0.912$) showed strong correlations, while most nutrients had moderate correlation coefficient values: the highest value was for MUFA ($r = 0.762$) and the lowest value was for total fibre ($r = 0.400$).

Figure 1 shows the good agreement, according to Bland–Altman plots, between the intakes of energy and macronutrients (energy-adjusted) from the FFQ and 3 d WDR. The mean difference (agreement range) observed between reported and registered data was 636.8 (−4823.3, 6096.9) kJ for energy, −2.9 (−45.8, 40.1) g for protein, 27.1 (−62.6, 116.8) g for carbohydrate and 7.5 (−20.9, 35.9) g for total lipids. Ten patients (13.8%) were identified outside the limits of agreement. A higher proportion of males (80.0% *v.* 38.7%; $P = 0.036$) and patients with poor glycaemic control (defined by HbA1c values; 9.7 (SD 2.3) % *v.* 8.2 (SD 1.8) %; $P = 0.028$) were observed in these patients as compared with patients within the limits of agreement (n 62). We did not observe other between-group differences.

Considering urinary urea-N output as a biomarker for protein intake, no differences were observed between data from the FFQ (96.2 (SD 39.2) g) and the biomarker (100.1 (SD 29.0) g; $P = 0.368$), or between data from the 3 d WDR (99.1 (SD 37.1) g) and the biomarker ($P = 0.792$). Figure 2 shows graphically (Bland–Altman plots) that the FFQ may be used as an alternative method to the 3 d WDR: the mean differences (agreement range) in protein intake obtained by the biomarker *v.* the FFQ (−3.8 (−60.1, 52.4) g) and *v.* the 3 d WDR (−1.0 (−59.7, 57.7) g) were not different ($P = 0.551$). Regarding estimated

Table 3 Energy, macronutrient and fibre intakes, glycaemic index and glycaemic load estimated from the second FFQ and the mean of 3 d WDR in Brazilian patients with type 2 diabetes mellitus included in the validity study (n 72)

Nutrient	FFQ		WDR		% difference†	P value	Pearson correlation‡		
	Mean or median	sd or IQR	Mean or median	sd or IQR			Crude data	Adjusted§	De-attenuated
Energy (kJ)	9102.3	3202.0	8465.9	2564.3	6.9	0.052	0.474**	—	0.671
Protein (g)	96.2	39.2	99.1	37.1	−3.0	0.536 ¶	0.432**	0.383**	0.597
Carbohydrate (g)	246.1	195.7–299.1	235.5	178.2–290.2	4.3	0.060¶	0.398**	0.338*	0.543
Total fibre (g)	25.8	10.1	18.5	8.0	28.3	<0.001	0.215	0.271*	0.400
Soluble fibre (g)	9.1	3.6	6.6	2.6	27.4	<0.001	0.246*	0.185	0.302
Insoluble fibre (g)	16.5	6.8	11.7	6.1	29.1	<0.001	0.126	0.196	0.287
Total lipids (g)	81.2	27.2	73.7	27.1	9.2	0.010	0.534**	0.552**	0.855
SFA (g)	24.4	10.3	21.1	9.2	13.5	0.005	0.491**	0.434**	0.687
MUFA (g)	27.0	9.1	24.0	8.8	11.1	0.008	0.407**	0.457**	0.762
PUFA (g)	21.3	8.7	21.2	9.1	0.4	0.654	0.696**	0.683**	0.912
Trans-fatty acids	1.9	0.9	2.0	1.1	−5.2	0.630	0.329**	0.290*	0.549
Glycaemic index (%)	55.8	4.5	57.3	5.0	−2.6	0.041	0.236*	0.251*	0.481
Glycaemic load (g)	120.7	93.5–142.1	117.4	92.5–159.9	2.7	0.469¶	0.326**	0.308**	0.455

WDR, weighed diet record; IQR, interquartile range.

* $P < 0.05$; ** $P < 0.01$

†The energy and nutrients values were log-transformed to normalize the distribution and calculate the correlation coefficients.

‡Difference (expressed by %) = [(value from FFQ) − (value from 3 d WDR)]/(value from FFQ) × 100.

§Data adjusted for energy intake according to the residual method⁽¹⁾.

||Student's *t* test for paired samples.

¶Wilcoxon's *U* test for paired samples.

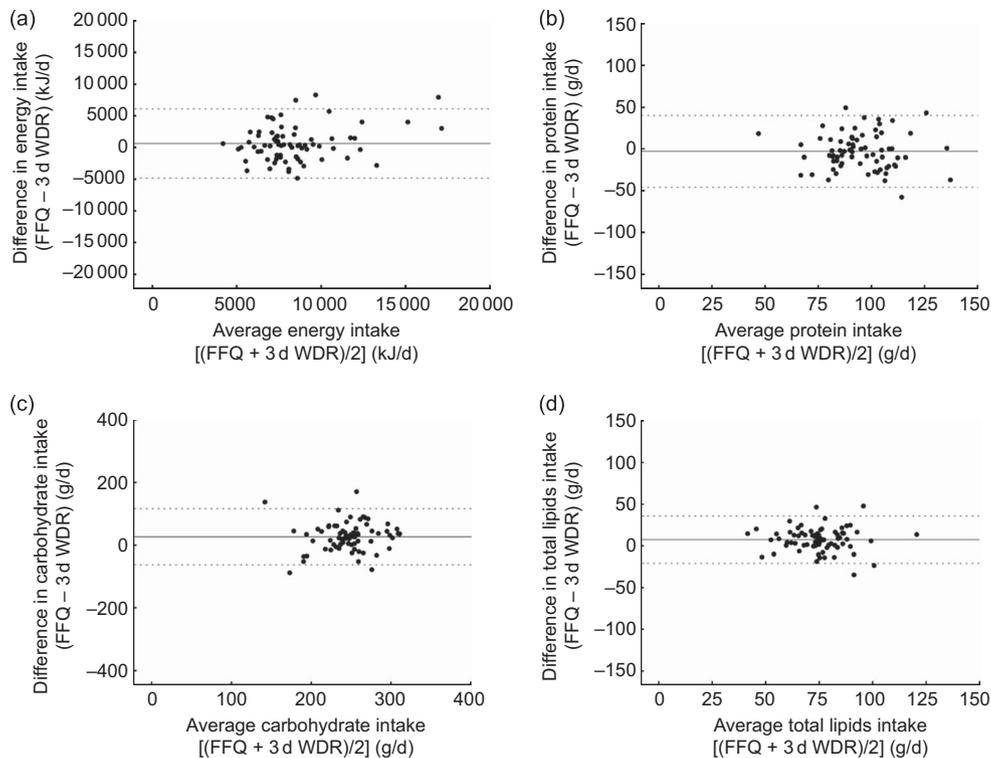


Fig. 1 Bland–Altman plots to evaluate the agreement between the values of nutrient intake reported from the second FFQ with those recorded from the 3 d weighed diet record (WDR): (a) energy, (b) protein, (c) carbohydrate and (d) total lipids; validity study among Brazilian patients with type 2 diabetes mellitus (n 72). The mean of the differences (—) and their limits of agreement (---) are shown. The macronutrient values were energy-adjusted

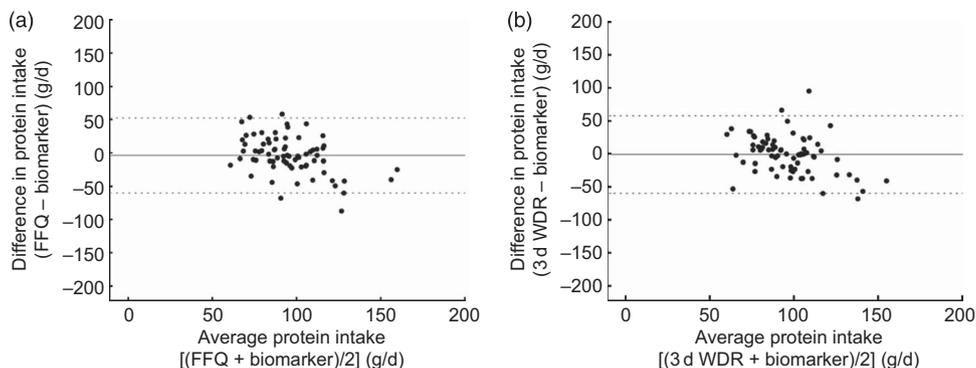


Fig. 2 Bland–Altman plots to evaluate the agreement between the values of protein intake estimated from: (a) the second FFQ with 24 h urinary urea-N output as biomarker and (b) mean of the 3 d weighed diet record (WDR) with 24 h urinary urea-N output as biomarker; validity study among Brazilian patients with type 2 diabetes mellitus (n 72). The mean of the differences (—) and their limits of agreement (---) are shown. The values of protein intake estimated from the FFQ and WDR were energy-adjusted

protein intake, the correlation coefficient was 0.597 ($P=0.001$) between the values obtained from the FFQ and the 3 d WDR, 0.414 ($P<0.001$) between values reported from the FFQ and estimated from the biomarker and 0.907 ($P<0.001$) between values obtained from the 3 d WDR and estimated from the biomarker. Therefore, the correlation between the protein intake from the FFQ and the true intake was 0.522 (95% CI 0.414, 0.597), according to the formula proposed by the method of triads⁽³⁵⁾.

Discussion

The FFQ constructed to evaluate the usual diet of Brazilian T2DM patients had adequate validity (moderate correlation values and appropriate agreement with the reference standards) and reproducibility to assess the past-month intakes of energy, macronutrients, GI and GL of patients with T2DM. This is the first FFQ elaborated based on the usual intake of patients with diabetes in Brazil.

In our study, some methodological precautions were taken into account: we tested the accuracy of the FFQ in a different sample from the one in which the FFQ was constructed⁽¹⁷⁾, but in the same population; we selected a sample of diabetic patients without previous experience in dietary records; we used reference standards, a 3 d WDR and urinary urea-N output as biomarker, previously standardized in patients with diabetes^(23,24) and largely used in diabetic patients by our research group^(36–39); and finally, we included the influence of seasonality on validity evaluation of the FFQ (applying the tested instrument throughout the year), because it is known that portion sizes and food types can vary according to seasonality⁽¹⁰⁾.

The correlation coefficients observed in the present study were within an acceptable range for calibration studies of diet, between 0.39 and 0.70⁽¹⁾, although the energy adjustment method reduced the correlation values in the reproducibility (see Table 2) and validity (see Table 3) studies. Possibly, this occurs when the variability of the nutrient is affected by systematic errors of under-recording or over-reporting of food consumption⁽¹⁾. Our results were similar to those of other studies that evaluated FFQ performance^(13,40,41).

We observed differences higher than 10% between intakes from the FFQ and 3 d WDR for some nutrients that could be explained by under-recording in the WDR^(42,43) or by overestimation by the FFQ, especially for fibre intake (~28%). In fact, previous studies have demonstrated that FFQ tend to overestimate energy and nutrient intakes compared with different dietary assessment methods^(44–46). The food groups present in the FFQ that could contribute to an overestimation of fibre intake are 'vegetables and legumes' and 'fruits'. In future studies, the inclusion of cross-check questions in the FFQ about intake of these food groups will be necessary to adjust the consumption frequency accordingly⁽⁴⁷⁾.

An additional assessment using a biochemical measure can be extremely valuable, considering that no dietary measure is without error⁽¹⁾. In this sense, the method of triads is a technique that has been used in studies to validate dietary nutrient intakes^(48–50). This method adds a third variable – a biomarker – with an error independent from that of the FFQ and the reference method (3 d WDR) to assess the performance to estimate the true (but unknown) intake by calculating the validity coefficient (ρ)⁽⁵¹⁾. In fact, biomarkers should be used as additional measures because not all nutrients have biological markers and many are influenced by factors other than intake, such as bioavailability, metabolism and genetic factors⁽³⁾. Our result from the correlation of the FFQ measurement with the true intake for protein ($\rho = 0.522$) was moderate and similar to that described by other authors^(52,53).

Regarding the reproducibility of the FFQ, an important aspect that influences the results is the time elapsed between applications of FFQ. If the interval is too short, the

reproducibility could be overestimated, since the participant remembers the answers of the first questionnaire. On the other hand, long intervals can reduce the correlations as a consequence of a real change in dietary patterns⁽¹²⁾. In this sense, it is suggested that short-term reproducibility studies should be performed with a time interval of 15–45 d⁽⁵⁴⁾. In our study, the FFQ was validated for assessment of habitual diet of the previous month (short term).

When we analysed the relative validity of the FFQ, significant correlations were observed for most nutrients considered and greater values were obtained after the de-attenuation procedure. These results are in accordance with the known influence of daily intra- and inter-individual variability of intake⁽¹⁾ that has been observed by others^(40,55).

Some limitations of the present study can be identified. We did not evaluate other biomarkers apart from protein intake. Although we have used the estimation of protein intake from urinary urea-N as a marker of compliance with the WDR technique in many studies^(23,24,36–39) to confirm the adequacy of dietary records, future comparisons with other biomarkers, such as serum fatty acids and micronutrients or energy expenditure, must however be performed. Another possible limitation is that in the current study reproducibility data were derived from a relatively short-term period. Long-term reproducibility of the instrument using multiple WDR during at least 1 year and the FFQ performance for micronutrients should be also evaluated.

Conclusion

In conclusion, we demonstrated that the quantitative FFQ previously constructed was valid and precise to assess the usual diet of patients with T2DM. In addition, this easily applied FFQ can replace the WDR technique, a more laborious dietary tool.

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References

1. Willett WC (1998) *Nutritional Epidemiology*. Oxford: Oxford University Press.
2. Biró G, Hulshof KF, Ovesen L *et al.* EFCOSUM Group (2002) Selection of methodology to assess food intake. *Eur J Clin Nutr* **56**, Suppl. 2, S25–S32.
3. Jenab M, Slimani N, Bictash M *et al.* (2009) Biomarkers in nutritional epidemiology: applications, needs and new horizons. *Hum Genet* **125**, 507–525.
4. Fisberg RM, Marchiori DML & Colucci ACA (2009) Assessment of food consumption and nutrient intake in clinical practice. *Arq Bras Endocrinol Metab* **53**, 617–624.
5. Bantle JP, Wylie-Rosett J, Albright AL *et al.* (2008) Nutrition recommendations and interventions for diabetes: a position statement of the American Diabetes Association. *Diabetes Care* **31**, Suppl. 1, S61–S78.
6. American Diabetes Association (2002) Standards of medical care in diabetes. *Diabetes Care* **35**, Suppl. 1, S11–S63.
7. Gross JL, Kramer CK, Leitão CB *et al.*; Diabetes and Endocrinology Meta-analysis Group (2011) Effect of antihyperglycemic agents added to metformin and a sulfonylurea on glycemic control and weight gain in type 2 diabetes: a network meta-analysis. *Ann Intern Med* **154**, 672–679.
8. Mendes ABV, Fittipaldi JAS, Neves RCS *et al.* (2010) Prevalence and correlates of inadequate glycemic control: results from a nationwide survey in 6,671 adults with diabetes in Brazil. *Acta Diabetol* **47**, 137–145.
9. Cardoso MA (2007) Desenvolvimento, validação e aplicações de questionários de frequência alimentar em estudos epidemiológicos. In *Epidemiologia Nutricional*, 1st ed., pp. 201–212 [G Kac, R Sichieri and D Gigante, editors]. Rio de Janeiro: Fiocruz/Atheneu.
10. Slater B, Philippi S & Marchioni D (2003) Validação de questionários de frequência alimentar – QFA: considerações metodológicas. *Rev Bras Epidemiol* **6**, 200–208.
11. Maroni BJ, Steinman TL & Mitch WE (1985) A method for estimating nitrogen intake of patients with chronic renal failure. *Kidney Int* **2**, 58–65.
12. Cade J, Thompson R, Burley V *et al.* (2002) Development, validation and utilization of food-frequency questionnaires – a review. *Public Health Nutr* **5**, 567–587.
13. Riley MD & Blizzard L (1995) Comparative validity of a food frequency questionnaire for adults with IDDM. *Diabetes Care* **18**, 1249–1254.
14. Yamaoka K, Tango T, Watanabe M *et al.* (2000) Validity and reproducibility of a semi-quantitative food frequency questionnaire for nutritional education of patients of diabetes mellitus (FFQW65). *Nihon Kosho Eisei Zasshi* **47**, 230–244.
15. Coulibaly A, Turgeon O'Brien H & Galibois I (2009) Validation of an FFQ to assess dietary protein intake in type 2 diabetic subjects attending primary health-care services in Mali. *Public Health Nutr* **12**, 644–650.
16. Hong S, Choi Y, Lee HJ *et al.* (2010) Development and validation of a semi-quantitative food frequency questionnaire to assess diets of Korean type 2 diabetic patients. *Korean Diabetes J* **34**, 32–39.
17. Sarmiento RA, Riboldi BP, Rodrigues TC *et al.* (2013) Development of a quantitative food frequency questionnaire for Brazilian patients with type 2 diabetes. *BMC Public Health* **13**, 740.
18. Chobanian AV, Bakris GL, Black HR *et al.* (2003) Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension* **42**, 1206–1252.
19. Gross JL, Azevedo MJ, Silveiro SP *et al.* (2005) Diabetic nephropathy: diagnosis, prevention, and treatment. *Diabetes Care* **28**, 164–176.
20. Associação Brasileira das Empresas de Pesquisa (2008) CCEB – Critério Brasil. <http://www.abep.org/novo/Content.aspx?SectionID=84> (accessed March 2009).
21. IPAQ Study Group (2005) International Physical Activity Questionnaire. <http://www.ipaq.ki.se/ipaq.htm> (accessed October 2009).
22. Hallal PC, Matsudo SM, Matsudo VKR *et al.* (2005) Physical activity in adults from two Brazilian areas: similarities and differences. *Cad Saude Publica* **21**, 573–580.
23. Moulin CC, Tiskievicz F, Zelmanovitz T *et al.* (1998) Use of weighed diet records in the evaluation of diets with different protein contents in patients with type 2 diabetes. *Am J Clin Nutr* **67**, 853–857.
24. Vaz JS, Bittencourt M, Almeida JC *et al.* (2008) Protein intake estimated by weighed diet records in type 2 diabetic patients: misreporting and intra-individual variability using 24-hour nitrogen output as criterion standard. *J Am Diet Assoc* **108**, 867–872.
25. US Department of Agriculture, Agricultural Research Service (2006) *SR 17 Research Quality Nutrient Data. The Composition of Foods, Agricultural Handbook No. 8*. Washington, DC: US Department of Agriculture.
26. Lima DM (2006) *Tabela de Composição dos Alimentos – TACO. Versão II*, 2a ed. Campinas, SP: NEPA – UNICAMP.
27. Exler J, Lemar L & Smith J (2000) Fat and Fatty Acid Content of Selected Foods Containing Trans-Fatty Acids. http://www.ars.usda.gov/SP2UserFiles/Place/12354500/Data/Classics/trans_fa.pdf (accessed March 2007).
28. Slover HT, Thompson JR, Davis CS *et al.* (1985) Lipids in margarines and margarine-like foods. *J AOAC Int* **62**, 775–786.
29. Van Poppel G, Van Erp-Baart M-A, Leth T *et al.* (1998) Trans fatty acids in foods in Europe: the TRANSFAIR Study. *J Food Compos Anal* **11**, 112–136.
30. Schakel S, Sievert YA & Buzzard IM (2001) Dietary fiber values for common foods. In *CRC Handbook of Dietary Fiber in Human Nutrition*, pp. 615–648 [GA Spiller, editor]. Boca Raton, FL: CRC Press.
31. Atkinson FS, Foster-Powell K & Brand-Miller JC (2008) International tables of glycemic index and glycemic load values. *Diabetes Care* **31**, 1–58.
32. Friedewald WT, Levy RI & Fredrickson DS (1972) Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin Chem* **18**, 499–502.
33. Latner AL (1975) Protein metabolism. In *Clinical Biochemistry*, 7th ed., pp. 147–234 [A Cantarow and M Trumper, editors]. Philadelphia, PA: WB Saunders Company.
34. Bland JM & Altman DG (1999) Measuring agreement in method comparison studies. *Stat Methods Med Res* **8**, 135–160.
35. Kaaks RJ (1997) Biochemical markers as additional measurements in studies of the accuracy of dietary questionnaire measurements: conceptual issues. *Am J Clin Nutr* **65**, Suppl. 4, 1232S–1239S.
36. Almeida JC, Zelmanovitz T, Vaz JS *et al.* (2008) Sources of protein and polyunsaturated fatty acids of the diet and microalbuminuria in type 2 diabetes mellitus. *J Am Coll Nutr* **27**, 528–537.
37. Steemburgo T, Dall'Alba V, Almeida JC *et al.* (2009) Intake of soluble fibers has a protective role for the presence

- of metabolic syndrome in patients with type 2 diabetes. *Eur J Clin Nutr* **63**, 127–133.
38. Silva FM, Steemburgo T, de Mello VD *et al.* (2011) High dietary glyceic index and low fiber content are associated with metabolic syndrome in patients with type 2 diabetes. *J Am Coll Nutr* **30**, 141–148.
 39. de Paula TP, Steemburgo T, de Almeida JC *et al.* (2012) The role of Dietary Approaches to Stop Hypertension (DASH) diet food groups in blood pressure in type 2 diabetes. *Br J Nutr* **108**, 155–162.
 40. Cardoso MA, Kida AA, Tomita LY *et al.* (2001) Reproducibility and validity of a food frequency questionnaire among women of Japanese ancestry living in Brazil. *Nutr Res* **21**, 725–733.
 41. Fornés NS, Stringhini MLF & Elias BM (2003) Reproducibility and validity of a food-frequency questionnaire among low-income Brazilian workers. *Public Health Nutr* **6**, 821–827.
 42. Goris AH, Westerterp-Plantenga MS & Westerterp KR (2000) Underreporting and underrecording of habitual food intake in obese men: selective underreporting of fat intake. *Am J Clin Nutr* **71**, 130–134.
 43. Scagliusi FB, Ferrioli E, Pfrimer K *et al.* (2008) Underreporting of energy intake in Brazilian women varies according to dietary assessment: a cross-sectional study using doubly labeled water. *J Am Diet Assoc* **108**, 2031–2040.
 44. Pereira GA, Genaro PS, Santos LC *et al.* (2009) Validation of a food frequency questionnaire for women with osteoporosis. *J Nutr Health Aging* **13**, 403–407.
 45. Zanolla AF, Olinto MTA, Henn RL *et al.* (2009) Avaliação de reprodutibilidade e validade de um questionário de frequência alimentar em adultos residentes em Porto Alegre, Rio Grande do Sul, Brasil. *Cad Saude Publica* **25**, 840–848.
 46. Henn RL, Fuchs SC, Moreira LB *et al.* (2010) Development and validation of a food frequency questionnaire (FFQ-Porto Alegre) for adolescent, adult and elderly populations from Southern Brazil. *Cad Saude Publica* **26**, 2068–2079.
 47. Calvert C, Cade J, Barrett JH *et al.* (1997) Using cross-check questions to address the problem of mis-reporting of specific food groups on food frequency questionnaires. *Eur J Clin Nutr* **51**, 708–712.
 48. Pufulete M, Emery PW, Nelson M *et al.* (2002) Validation of a short food frequency questionnaire to assess folate intake. *Br J Nutr* **87**, 383–390.
 49. Andersen LF, Veierod MB, Johansson L *et al.* (2005) Evaluation of three dietary assessment methods and serum biomarkers as measures of fruit and vegetable intake, using the method of triads. *Br J Nutr* **93**, 519–527.
 50. McNaughton SA, Hughes MC & Marks GC (2007) Validation of a FFQ to estimate the intake of PUFA using plasma phospholipid fatty acids and weighed food records. *Br J Nutr* **97**, 561–568.
 51. Yokota RTC, Miyazaki ES & Ito MK (2010) Applying the triads method in the validation of dietary intake using biomarkers. *Cad Saude Publica* **26**, 2027–2037.
 52. Shai I, Rosner BA, Shahar DR *et al.* (2005) Dietary evaluation and attenuation of relative risk: multiple comparisons between blood and urinary biomarkers, food frequency, and 24-hour recall questionnaires: the DEARR Study. *J Nutr* **135**, 573–579.
 53. Mirmiran P, Esfahani FH, Mehrabi Y *et al.* (2010) Reliability and relative validity of an FFQ for nutrients in the Tehran Lipid and Glucose Study. *Public Health Nutr* **13**, 654–662.
 54. Burley V & Cade J (2000) Consensus document on the development, validation, and utilization of food frequency questionnaires. In Proceedings of the Fourth International Conference on Dietary Assessment Methods, Tuscon, Arizona, USA, September 17–20, 2000. *Public Health Nutr* **5**, 815–1109.
 55. Takachi R, Ishihara J, Iwasaki M *et al.* (2011) Validity of a self-administered food frequency questionnaire for middle-aged urban cancer screenees: comparison with 4-d weighed dietary records. *J Epidemiol* **21**, 447–458.