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Research Article

Long-Term Reproducibility and Calibration of a Quantitative Food Frequency Questionnaire Designed for Patients with Type 2 Diabetes Mellitus from Southern Brazil

Roberta Aguiar Sarmento[1,2], Bárbara Pelicioli Riboldi[2,3] and Jussara Carnevale de Almeida[1,2,4]*

[1]Endocrinology Division, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

[2]Food and Nutrition Research Center, Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

[3]Graduate Studies Program in Epidemiology, Faculdade de Medicina, Universidade Federal do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

[4]Department of Nutrition, Faculdade de Medicina, Universidade Federal do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

***Corresponding Author:** Jussara Carnevale de Almeida, Serviço de Endocrinologia do Hospital de Clínicas de Porto Alegre, Rua Ramiro Barcelos, Porto Alegre, RS, Brazil.

Received: November 27, 2019; **Published:** December 09, 2019

Abstract

Background: Recently, a quantitative food frequency questionnaire (FFQ) was constructed and validated in patients with type 2 diabetes mellitus (T2DM) from Southern Brazil, and the short-term reproducibility (1-month) of this instrument was evaluated. The present study continues this research and was designed to calibrate and evaluate the long-term reproducibility (1-year) of the FFQ for assessment of the usual diet of patients with T2DM.

Methods: Cross-sectional survey using two quantitative FFQ (1-year interval) supported by a food photograph portfolio and 5-day weighed diet records (WDR). To evaluate the FFQ reproducibility, data from the first and second FFQs were compared by Student's t-test or Wilcoxon's U test for paired samples, and Pearson correlation coefficients were calculated. Calibration was performed using a linear regression model. Energy and nutrient intake values from WDR were used as dependent variables, and data from the FFQ were used as independent variables. Values for each nutrient were calibrated using the following equation: calibrated value = $\alpha + \lambda Q$ (α = regression constant, λ = slope of the regression line or "calibration factor", and Q = estimated energy and nutrient intake from the FFQ).

Results: From a total of 88 eligible patients in the original study, 70 were included in the evaluation of FFQ reproducibility and 57 provided data for the calibration study. Mean nutrient intake values reported in the second FFQ did not differ from those of the first FFQ. Only protein, monounsaturated fatty acids, sodium, and iron were different from corresponding values between the first and second FFQs ($P < 0.05$). All correlation coefficients were significant before and/or after adjustment for energy ($P < 0.05$), ranging from 0.627 (potassium) to 0.243 (cholesterol). Calibration coefficients estimated by linear regression of the 5-day WDR on the second FFQ measurements ranged from 0.11 (glycaemic load) to 0.57 (calcium).

Conclusion: Results confirm that this FFQ had adequate reproducibility to assess past-year intakes of energy, nutrients, glycaemic index, and glycaemic load, and will enable the conduction of prospective studies to evaluate the relationship between food intake, achievement of recommended therapeutic targets, and development of complications in patients with T2DM in southern Brazil.

Keywords: *Type 2 Diabetes Mellitus; Nutritional Epidemiology; Food Frequency Questionnaire; Reproducibility; Calibration*

Background

The influence of diet on the development of human disease has been the central focus of nutritional epidemiology [1]. In the case of diabetes, the importance of individual nutrients and foods for disease management has been demonstrated in clinical trials [2-4], but the overall effect of diet in achieving recommended therapeutic targets is not fully elucidated [5].

To investigate the association between dietary components and diabetes management and/or development of chronic complications, the dietary evaluation should cover a long period (months or years), as is the case of the food frequency questionnaire (FFQ) [1]. The FFQ should be based on a specific population, and its validity, calibration, and reproducibility should always be tested [1]. Validity is examined by comparing FFQ data with a reference method, biomarkers, or both [6]. To evaluate reproducibility, the FFQ should be tested at least on two separate occasions [7]. Finally, calibration is used to correct intake data obtained by the FFQ (test method) according to the reference method [8].

Recently, a quantitative FFQ was constructed [9] and validated [10] in patients with type 2 diabetes mellitus (T2DM) from Southern Brazil, and the short-term reproducibility (1-month) of this instrument was evaluated [10]. The present study continues this research and was designed to calibrate and evaluate the long-term reproducibility (1-year) of the FFQ for assessment of the usual diet of patients with T2DM.

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 [11]. 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 undergone any dietary assessment.

The inclusion criteria were: age < 80 years, serum creatinine < 2.0 mg/dL and body mass index < 40.0 kg/m^2. 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 Hospital de Clínicas de Porto Alegre. Written informed consent was obtained from all patients.

Patients underwent 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. Increased urinary albumin excretion (UAE) was considered in the presence of UAE ≥ 14 mg/l in a random spot urine collection, or ≥ 30 mg/24 h. This diagnosis was always confirmed [5]. 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 [12] and physical activity level was classified according to the short version of the International Physical Activity Questionnaire [13], culturally adapted to the Brazilian population [14]. Physical activity was graded into three levels: low, moderate and high, according to activities during a typical week [13]. The body weight and height of patients (wearing light clothing and no shoes) were obtained, with measurements recorded to the nearest 100g for weight and to the nearest 0.1 cm for height. Body mass index (kg/m^2) was then calculated. Waist circumference was measured at the midpoint between the iliac crest and the last floating rib, using a flexible and non-stretchable fiberglass tape.

Dietary assessment

The patients' usual diet was assessed by the FFQ (study factor), previously constructed [9] and validated [10] in patients from Southern Brazil, and by 5-day weighed diet records (WDR), used as a relative reference. The FFQ consisted of the 98 most commonly consumed food items and covered the past 12 months [9,10]. A portfolio with photographs of each included food item and its portion sizes was used to assist the patients in identifying the consumed portions.

The FFQ was applied by a nutritionist in an interview, twice, with a 1-year interval. Between these visits, the patients underwent a 5-day WDR (four non-consecutive weekdays and one day off) [15]. Compliance with the WDR technique was confirmed by comparison between the protein intakes estimated from the WDR and the 24 h urinary urea-N output [16]. To be included in calibration 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 [17].

The food intakes reported in the dietary instruments (FFQ and 5-day WDR) were converted into daily intakes and their nutritional composition was calculated in the Nutribase Clinical® software (CyberSoft Inc., Phoenix, AZ, USA), which is based on food composition data from the U.S. Department of Agriculture [18]. The amount of trans-fatty acids was derived from the Tabela de Composição dos Alimentos – TACO [19], the US Department of Agriculture [20], Slover., *et al.* [21] and the TRANSFAIR Study [22]. The total, soluble and insoluble dietary fibre contents were estimated from data available in the CRC Handbook of Dietary Fiber in Human Nutrition [23]. The glycaemic index (GI) and glycaemic load (GL) were obtained from international tables [24]. When the GI of foods present in the instruments was not found, we used data for 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 Jaffé'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 triglycerides were measured by enzymatic colorimetric methods; and HDL-cholesterol was determined by the homogeneous direct method. LDL-cholesterol was calculated using the Friedewald formula [25] only for patients with triglyceride values < 400 mg/dl.

On the third day of the WDR, urea was measured in a 24h urine collection. Collection started on the morning of the third day with the second morning urine and lasted until the fourth day, at the same hour, with the first morning urine. Completeness of urine collection was confirmed by 24h creatinine measurements: 700 to 1500 mg/24h for women and 1000 to 1800 mg/24h for men [26]. Protein intake was estimated from 24 h urinary urea-N output and calculated using Maroni's formula [16]. Urinary albumin excretion was measured by immunoturbidimetry (MicroAlb Sera-Pak® Immunomicroalbuminuria; Bayer, Tarrytown, NY, USA) in a Cobas Mira Plus® system (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. Gaussian distribution was verified by the one-sample Shapiro-Wilk test. For descriptive analysis, the chi-squared test, Student's *t*-test and the Mann-Whitney test for independent samples were used to test for differences in demographic, lifestyle and metabolic parameters of patients included in the reproducibility study, as compared with those included in calibration study. Data analyses were performed in SPSS Version 20.0 and SAS (Statistical Analysis System, SAS Institute Inc., Cary, NC), version 9.4. The type I error rate was fixed at $P < 0.05$ (two-tailed).

To evaluate the FFQ reproducibility, data from the first and second FFQs 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]. Data were log-transformed before analyses to normalize distributions.

In the calibration study, data from the second FFQ and 5-day WDR were evaluated. Calibration was performed using a linear regression model. Energy and nutrient intake values from WDR were used as dependent variables, and estimates based on data from the FFQ were used as independent (predictor) variables. Values for each nutrient were calibrated using the following equation: $calibrated\ value = \alpha + \lambda Q$, where α is the regression constant, λ is the slope of the regression line or "calibration factor", and Q is the estimated energy and nutrient intake from the FFQ.

Results

Patients

Out of a total of 88 participants eligible for the original study [10], 18 patients (20.4%) agreed to participate but did not return for another visit to complete the second FFQ. Furthermore, 13 patients (14.8%) performed an unsatisfactory WDR and were not included in the calibration evaluation. Therefore, 70 patients were included for the reproducibility evaluation and 57 patients provided complete data for the calibration study. The demographic, clinical, anthropometric and laboratory characteristics of the patients included in each study are shown in table 1. We did not observe differences in characteristics between the patients included in the reproducibility study and patients included in the calibration evaluation ($P > 0.100$ for all analyses).

Characteristics	Reproducibility study	Calibration study	*P* value
n	70	57	
Female sex	42 (60.0)	30 (52.6)	0.469*
Age (years)	62.6 ± 8.7	62.3 ± 8.5	0.832†
Diabetes duration (years)	10.0 (4.0 - 17.5)	11.0 (4.0 - 20.0)	0.665‡
White skin colour (self-reported)	49 (70.0)	40 (70.2)	0.980*
Years of education	6.5 (5.0 - 11.0)	8.0 (5.0 - 11.0)	0.539‡
Hypertension	63 (90.0)	50 (87.7)	0.657*
Increased UAE	21 (30.4)	17 (30.4)	0.943*
Diabetes treatment			
Diet	1 (1.4)	1 (1.8)	0.826*
Oral agents	32 (45.7)	22 (38.6)	
Insulin and oral agents	37 (52.9)	34 (59.6)	
Economic status: middle class	30 (42.8)	20 (35.1)	0.877*
Current smoking	4 (5.7)	2 (3.5)	0.787*
Physical activity: low level	38 (55.9)	30 (53.6)	0.896*
Body mass index (kg/m^2)	29.7 ± 4.4	29.8 ± 4.6	0.954†
Waist circumference (cm)			
Male	102.9 ± 10.9	103.2 ± 11.3	0.934†
Female	99.4 ± 9.9	99.8 ± 10.9	0.853†
Fasting plasma glucose (mg/dl)	142.7 ± 55.0	145.1 ± 55.6	0.818†
HbA1c (%)	8.5 ± 2.0	8.6 ± 2.0	0.699†
Total cholesterol (mg/dl)	184.2 ± 48.4	182.9 ± 48.0	0.892†
HDL-cholesterol (mg/dl)			
Males	41.3 ± 12.3	46.4 ± 16.4	0.203†
Females	49.9 ± 13.4	45.6 ± 11.0	0.175†
LDL-cholesterol (mg/dl)	109.2 ± 38.2	109.1 ± 39.1	0.984†
Triglycerides (mg/dl)	120.0 (94.0 - 177.5)	124.5 (95.3 - 181.0)	0.733‡
Serum creatinine (mg/dl)	0.9 ± 0.3	0.9 ± 0.3	0.806†
Urinary albumin excretion (mg/dl)	8.2 (3.0 - 23.5)	13.7 (3.2 - 52.1)	0.936‡

Table 1: *Demographic, clinical, anthropometric, and laboratory characteristics of patients included in reproducibility and calibration studies*

Data are expressed as means ± standard deviation, median (interquartile range), or n (%).

**Chi-square test; †Student's t-test; ‡Mann-Whitney test.*

Reproducibility study (long term)

The daily intake data obtained from the first and second FFQs were compared and are shown in table 2. The mean values of nutrient intake reported from the first FFQ for protein (5.8%), monounsaturated fatty acids (6.7%), sodium (5.9%), and iron (6.7%) were different than corresponding values from the second FFQ ($P < 0.05$ for all comparisons).

The reported intakes of other macro- and micronutrients 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/or after energy adjustment ($P < 0.05$ for all analyses). Most nutrients showed moderate correlation values: the highest value was for potassium ($r = 0.627$), and the lowest was for cholesterol ($r = 0.243$).

Nutrient	First FFQ	Second FFQ	*P* value†	Pearson correlations‡	
				Crude data	Adjusted§
Energy (kcal)	2105.3 ± 700.7	2113.9 ± 617.7	0.914	0.517*	-
Protein (g)	92.2 ± 16.2	86.8 ± 13.1	0.011	0.596*	0.310*
Carbohydrate (g)	259.3 ± 38.4	263.0 ± 44.1	0.537	0.438*	0.233
Total fibre (g)	25.1 ± 6.6	24.7 ± 7.1	0.613	0.560*	0.457*
Soluble fibre (g)	8.8 ± 2.3	8.4 ± 2.2	0.177	0.531*	0.346*
Insoluble fibre (g)	16.1 ± 5.0	16.2 ± 5.3	0.819	0.507*	0.424*
Total lipids (g)	79.1 ± 14.3	81.9 ± 17.6	0.242	0.449*	0.345*
Saturated fatty acids (g)	23.5 ± 5.9	22.8 ± 6.4	0.462	0.580*	0.431*
Monounsaturated fatty acids (g)	26.2 ± 5.5	28.1 ± 7.1	0.031	0.556*	0.430*
Polyunsaturated fatty acids (g)	21.4 ± 7.6	23.3 ± 8.8	0.110	0.234	0.415*
Trans-unsaturated fatty acids	1.9 ± 0.6	1.7 ± 0.6	0.245	0.501*	0.334*
Glycaemic index (%)	55.7 ± 4.6	55.2 ± 5.1	0.425	0.464*	0.440*
Glycaemic load (g)	127.8 ± 26.8	123.7 ± 29.2	0.378	0.452*	0.082
Cholesterol (mg)	243.1 ± 79.4	223.6 ± 75.3	0.079	0.579*	0.243*
Vitamin C	202.9 (132.3 - 259.8)	202.8 (127.3 - 252.8)	0.736	0.599*	0.572*
Calcium (mg)	895.4 ± 309.0	850.2 ± 289.0	0.191	0.585*	0.573*
Magnesium (mg)	335.5 ± 61.6	343.5 ± 70.3	0.275	0.547*	0.561*
Sodium (mg)	1998.7 ± 463.6	1881.0 ± 442.3	0.049	0.529*	0.423*
Iron (mg)	15.0 ± 2.2	14.0 ± 2.5	0.003	0.559*	0.363*
Potassium (mg)	3512.0 ± 715.6	3528.9 ± 752.8	0.842	0.627*	0.486*

Table 2: *Energy intake, macro- and micronutrients, fibre, glycaemic index, and glycaemic load estimated from the two food frequency questionnaires (FFQ) at a 1-year interval, in patients with type 2 diabetes mellitus (reproducibility study, n = 70).*

*Data are expressed as means ± standard deviation or median (interquartile range). †Student's t-test for paired samples or Wilcoxon U-test for paired samples. ‡Energy and nutrient values were log-transformed to normalize distribution and calculate correlation coefficients. §Data adjusted for energy intake according to the residuals method [1]. *P < 0.05.*

Calibration study

The results of calibration are presented in table 3. Values ranged from 0.11 (glycaemic load) to 0.57 (calcium). Calibration results were statistically significant for most nutrients. As expected, the mean calibrated values based on data from the FFQ were very similar to the energy-adjusted mean values from the 5-day WDR and were associated with a considerable reduction in standard deviation.

Nutrient	Regression constant α (95% CI)	Calibration factor λ (95% CI)	FFQ†‡	WDR†‡	Calibrated FFQ†
Energy (kcal)	1194.1 (750.5 - 1637.8)	0.37 (0.17 - 0.57)	2136.6 ± 577.5	1993.8 ± 480.0	1993.8 ± 216.1
Protein (g)	51.4 (24.3 - 78.4)	0.51 (0.21 - 0.81)	88.8 ± 30.3	96.9 ± 29.0	96.9 ± 6.9
Carbohydrate (g)	156.0 (106.4 - 205.6)	0.30 (0.12 - 0.48)	268.5 ± 75.4	235.9 ± 70.5	235.9 ± 13.2
Total fibre (g)	10.0 (3.8 - 16.9)	0.36 (0.12 - 0.60)	24.7 ± 8.3	18.8 ± 8.0	18.8 ± 2.6
Soluble fibre (g)	3.1 (1.2 - 5.1)	0.41 (0.18 - 0.63)	8.5 ± 2.6	6.6 ± 2.5	6.6 ± 0.9
Insoluble fibre (g)	6.4 (2.1 - 10.8)	0.35 (0.10 - 0.61)	16.2 ± 6.0	12.1 ± 6.0	12.1 ± 1.9
Total lipids (g)	50.1 (32.8 - 67.4)	0.28 (0.07 - 0.49)	80.5 ± 27.4	72.7 ± 18.2	72.7 ± 4.4
Saturated fatty acids (g)	12.1 (7.7 - 16.5)	0.36 (0.17 - 0.54)	22.9 ± 10.1	20.3 ± 6.5	20.3 ± 2.3
Monounsaturated fatty acids (g)	14.3 (8.2 - 20.4)	0.35 (0.13 - 0.56)	28.1 ± 10.6	24.0 ± 7.0	24.0 ± 2.3
Polyunsaturated fatty acids (g)	12.8 (8.0 - 17.6)	0.39 (0.18 - 0.60)	21.8 ± 8.3	21.4 ± 6.7	21.9 ± 2.6
Trans-unsaturated fatty acids	1.1 (0.4 - 1.7)	0.49 (0.13 - 0.84)	1.7 ± 0.8	1.9 ± 0.9	1.9 ± 0.3
Glycaemic index (%)	40.3 (20.3 - 60.4)	0.31 (-0.05 - 0.67)	55.5 ± 4.5	57.4 ± 6.1	57.4 ± 1.4
Glycaemic load (g)	105.5 (82.2 - 128.9)	0.11 (-0.08 - 0.29)	125.7 ± 38.2	118.8 ± 34.7	118.8 ± 3.0
Cholesterol (mg)	194.5 (109.3 - 279.8)	0.17 (-0.18 - 0.53)	230.7 ± 112.9	234.8 ± 127.9	234.8 ± 12.6
Vitamin C	50.6 (13.6 - 87.5)	0.23 (0.07 - 0.39)	206.1 ± 102.8	97.6 ± 69.9	97.6 ± 23.1
Calcium (mg)	216.9 (6.2 - 427.7)	0.57 (0.34 - 0.81)	856.1 ± 343.1	709.2 ± 372.1	709.2 ± 163.4
Magnesium (mg)	123.9 (41.5 - 206.3)	0.55 (0.31 - 0.78)	348.6 ± 103.0	314.3 ± 105.2	314.3 ± 37.8
Sodium (mg)	1439.9 (915.3 - 1964.5)	0.32 (0.04 - 0.59)	1876.9 ± 619.7	2031.6 ± 701.2	2031.6 ± 149.4
Iron (mg)	11.4 (6.7 - 16.1)	0.20 (-0.12 - 0.53)	14.1 ± 4.0	14.3 ± 4.4	14.3 ± 0.5
Potassium (mg)	1230.5 (289.0 - 2172.0)	0.46 (0.21 - 0.72)	3633.2 ± 1089.5	2918.3 ± 1076.4	2918.2 ± 331.9

Table 3: *Energy intake, macronutrients, fibre, glycaemic index, and glycaemic load estimated from the second food frequency questionnaire (FFQ) versus a 5-day mean of weighed diet records (WDR) in patients with type 2 diabetes mellitus (calibration study, n = 57).*

†Data are expressed as means ± standard deviation. ‡Data adjusted for energy intake according to the residuals method [1].

Discussion

The present FFQ, constructed to evaluate the usual diet of Brazilian patients with T2DM, had adequate reproducibility to assess past-year intakes of energy, most nutrients, GI, and GL. This is the first FFQ developed on the basis of usual dietary intake of patients with T2DM in Brazil.

In our study, some methodological precautions were taken into account: we selected a sample of patients with diabetes and without previous experience in dietary records; we used reference standards (WDR and urinary urea-N output) previously standardized in patients with diabetes [15,17]; we included the influence of seasonality on reproducibility evaluation of the FFQ, applying the tested

instrument throughout the year [27] and finally, the nutrients were adjusted for energy using the residual method [1]. Adjustment for energy is recommended both by the need to consider isocaloric models and to control embedded error in the methods [1].

Analysis of reproducibility revealed that mean intake of energy, macro- and micronutrients, fibre, glycaemic index and glycaemic load estimated from the two FFQs were not different. We observed statistical differences between the two FFQ for protein, monounsaturated fatty acids, sodium, and iron (See table 2). However, the differences were small (< 7%) and not clinically relevant.

Reproducibility was also analysed using Pearson correlations. All nutrients with crude data and/or data adjusted for energy showed coefficients between 0.24 and 0.62, although the energy adjustment method reduced correlation values in the reproducibility study (See table 2). Possibly, this occurs when the variability of the nutrient is affected by systematic errors of under-recording or over-reporting of food consumption [1].

In the literature, correlation coefficients between 0.40 and 0.70 are considered indicative of good reproducibility of the FFQ [1]. This is due to the fact the reproducibility may be affected by the time elapsed between FFQ applications [1]. If the interval is too short, such as a few days or weeks, reproducibility could be overestimated, as the participant remembers the answers of the first questionnaire. On the other hand, long intervals can reduce correlations as a consequence of a real change in dietary patterns or response variability [28]. In this study, the average time interval between interviews was 1 year, and this range could imply moderate correlation coefficients. Our results were similar to those of other studies that evaluated FFQ performance [29-31].

Calibration is useful for correcting errors in estimating food intake, particularly when dietary intake is the exposure variable of an association study between diet and disease [32]. This statistical method provides the coefficients required to correct the average values of energy intake and nutrients estimated by the test method (FFQ), resulting in values similar to those obtained by the reference method, the WDR [33]. In calibration by a linear regression model, the method used in this study, it is desired that the slope, represented by λ, be approximately 1.0. This indicates absence of bias in the questionnaire, i.e. average intake estimated through the FFQ will be equal to the average estimated by the reference method [33]. As in other calibration studies [34-37], slope values less than 1.0 were observed in the present study (See table 3).

To obtain greater λ coefficients, either the number of replicates of the reference method or the sample size must be increased [35]. The number of replicates used in our study (5 days) is greater than that commonly used in the literature [34-37], but less than "ideal". Capturing the daily variability of certain nutrients could take more than 5 days, as demonstrated by Basiotis., *et al*. who reported that the number of days of diet observation range from 3 (for calories) to 44 (for vitamin A) [38].

In fact, we chose to use the WDR in this study because it is widely recommended in the literature as the reference method for FFQ validation, because it discloses independent errors in the collection of diet information [27], even though it demands greater effort of the participants, who may cause changes in food intake to facilitate its registration [39]. Furthermore, we believe that the use of a 5-day WDR may increase the possibility of loss to follow-up, as was the case in this study. However, individuals lost to follow-up did not demonstrate significant differences in characteristics as compared with those who remained in the study (data not shown).

Conclusion

In conclusion, reproducibility results confirm that this FFQ will enable the conduction of prospective studies to evaluate the relationship between food intake, achievement of recommended therapeutic targets, and development of complications in patients with T2DM in southern Brazil. The use of calibration coefficients is recommended to correct for the measurement error of the FFQ, which can make it a more useful tool for studies designed to test for associations between diet and health outcomes.

Ethics Approval and Consent to Participate

This 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 Hospital de Clínicas de Porto Alegre. Written informed consent was obtained from all patients.

Consent for Publication

The final version of the manuscript has been approved for submission by all authors.

Availability of Data and Material

Not applicable.

Competing Interests

The authors do not have a conflict of interest.

Funding

This study was partially supported by Fundo de Incentivo à Pesquisa e Eventos – Hospital de Clínicas de Porto Alegre. R.A.S. received scholarships from Fundação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), and B.P.R., from Programa Institucional de Bolsas de Iniciação Científica - Conselho Nacional de Desenvolvimento Científico e Tecnológico.

Authors' Contributions

R.A.S. was responsible for study design, data collection, and preparation of the manuscript. B.P.R. questionnaires application and performed statistical analyses. J.C.A. contributed to the study design and each step of the research, as well as to proofreading of the manuscript. All authors reviewed the manuscript and approved the final version.

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Volume 15 Issue 1 January 2019
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