Development and Validation of a Novel Food-frequency Questionnaire for Hemodialysis Patients in Lucknow, India

Abstract

Introduction: Food-frequency questionnaire (FFQ) is a preferred tool for longitudinal dietary assessment and has been recently validated in patients on hemodialysis in other countries. As dietary habits vary vastly across regions, this study was planned to develop and validate a novel dialysis FFQ in northern India. Materials and Methods: Dietary recall data from patients on hemodialysis available from the previous year were used for identifying food items for inclusion in the FFQ. A nutrient database was created to estimate energy, protein, calcium, phosphorus, and potassium content of the foods included in the food list. The FFQ was validated against a 2-day dietary recall method (one predialysis, one on the dialysis day) in patients on maintenance hemodialysis in a tertiary care hospital in Lucknow, northern India. Results: Dietary recall data from 78 patients on hemodialysis were used for the generation of the FFQ. A total of 84 patients completed the validation study. All the nutrients measured by the FFQ correlated significantly with the means of the 2-day dietary record (r values 0.31-0.76) both in crude- and energy-adjusted intakes. De-attenuation further improved the correlation (0.35–0.80). Bland-Altman plots showed higher estimates by FFQ than by dietary recall. Cross-classification analysis showed correct classification in the exact or adjacent quintile (average 60%) by both methods and 2% gross misclassification. Weighted kappa showed fair agreement for energy intake and slight agreement for others. Conclusion: This novel semiquantitative FFQ is a valid tool for measuring energy and nutrient intakes in hemodialysis patients.

Keywords: Food-frequency questionnaire, hemodialysis, renal nutrition, validation

Introduction

The assessment of dietary intake is an important aspect in the management of patients with chronic kidney disease (CKD) on hemodialysis. While several methods exist, such as dietary recall, weighed food records, and food diaries, food frequency questionnaire (FFQ) is preferred for long-term diet assessment in epidemiologic studies.^[1,2] The use of FFQs in the hemodialysis population has recently been validated in a few studies from France and Indonesia.^[3,4] The target population being studied and nutrients of interest govern the design and development of an FFQ. In India, there are several regional variations in food intake, which makes it imperative that separate FFQs will need to be designed region-wise.^[5] In the case of patients with CKD, dietary intakes are modified by restrictions on salt, fluid, protein, and potassium intake, and further limited by the social and economic burden of the disease.

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cardiovascular and metabolic outcomes in Kerala, Gujarat, Uttar Pradesh, and South India.^[6-8] However, to our knowledge, no dialysis-specific FFQ has been developed so far in India. We intended to develop a FFQ for hemodialysis patients in Northern India, with a primary purpose of assessing the intake of the nutrients of interest to the nephrologist, such as protein, calcium, phosphorus, and potassium. Notably, no previous study has examined the dietary intake of phosphorus and potassium in Indian patients, and the data on protein intake in Indian hemodialysis patients are sparse, at best. A validated FFQ in this setting would serve an important role in further studies assessing protein-energy wasting and mineral-bone disease from this region. **Materials and Methods**

Different FFQs have been developed for use in the general population to study

Preparation of food list

The items for the food list were primarily procured from 24-h dietary recalls of 78

How to cite this article: Rao SN, Chandra A, Tiwari P, Mishra P. Development and validation of a novel food-frequency questionnaire for hemodialysis patients in Lucknow, India. Indian J Nephrol 2021;31:276-82.

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Received: 20-04-2019 **Revised:** 17-10-2019 **Accepted:** 17-11-2019 **Published:** 10-04-2021

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CKD patients collected in the year 2016–2017. The food list was expanded by dieticians with added local foods missing from the original list. The final food list comprised 154 items. These items were then divided into 9 food groups—cereals, pulses, milk and dairy, vegetables, (raw and cooked) and fruits, sweets and snacks, beverages, and protein supplements.

Does egg and meat include all animal proteins including fish?

Yes, egg and meat includes all animal protein including fish

Development of a nutrient database

The Indian Food Composition Table provided the reference standard for determining the nutrient content of raw ingredients used in the preparation of the food item.^[9] Recipes for all cooked items were collected from dialysis patients and their caregivers. These recipes were corroborated by the hospital's dietician and recipes found online on popular websites. Some of these items (roti, rice, pulses, khichdi, tea) were cooked in the kitchen of the institute for standardization.

Development of FFQ

The dietary data from the 78 participants were analyzed and all the food items which contributed to cumulative of 90% of the variance in energy, protein, calcium, phosphorus, and potassium were included in the FFQ, after performing multiple stepwise regression analyses. A total of 54 food items were included in the final FFQ generated from the food list. Frequency categories used were times per day, per week, per month, and per year. Interviewers were trained by the investigator in collecting information for the FFQ. Portion size estimation was aided by the use of cups, spoons, glasses, and discs of varying sizes.

Validation of the dialysis FFQ

Patients on hemodialysis at our tertiary care referral institute in Lucknow in northern India were recruited to the present study after written informed consent. The study was approved by the institute's ethics committee. The patients were recruited only if they had been on hemodialysis for longer than 1 year and had no intercurrent hospitalizations during the previous 3 months. Demographic and anthropometric parameters were noted by patient interview and physical examination. The patients were taught to fill a food diary in the local language and expected to fill 2-day food diaries, including one on dialysis day and one day prior to dialysis. The diaries were examined immediately after collection by the dietician to assess for its completeness, and any gaps were filled. The FFQ was administered by a trained dietician on the dialysis day, 2–4 weeks after collection of the 2-day dietary diary.

Statistical analyses

Descriptive analyses were carried out for the demographic and anthropometric parameters of the study subjects. Log transformation was done for all nutrient intakes. Energy adjustment by the residual method was performed by Willett's method, by computing residuals from regression analysis using nutrient intake as the dependent variable and total energy as the independent variable.^[10] The residuals were added to the expected nutrient intake for a participant with the mean energy intake to compute the energy-adjusted nutrient intakes.

For the validation of the FFQ, comparison with the 2-day dietary recall method was done by Pearson correlation, paired t-tests, cross-classification analysis, and Bland-Altman plots. De-attenuated values for Pearson correlation coefficients were taken using the multiplication factor $\{1 + [(\sigma_{\perp}^2/\sigma_{\perp}^2)/n]\}^{0.5}$, where n = 2 and (σ_w^2/σ_b^2) is the within-person variance divided by the between-person variance for each nutrient.^[10] Then, a cross-classification analysis was used to identify theparticipants who were correctly (same or adjacent quintile) and grossly misclassified (lowest quintile by one method and highest by the other, and weighted kappa statistics (κ_{μ}) were calculated). The following values for κ were used to evaluate the agreement of the two methodsgreater than 0.80-almost perfect, 0.61-0.80-substantial, 0.41-0.60-moderate, 0.21-0.40-fair, 0.00-0.20-slight, and <0.00-poor agreement, according to the system developed by Landis and Koch.[11] The Bland-Altman plots were used for visually assessing the agreement between the FFQ and the mean of 2-day dietary recall nutrient intakes. All the statistical analyses were carried out on SPSS software version 16.0 (IBM corporation, Chicago, IL, USA).

Results

The food items identified from the previous year's dietary recall data from the local hemodialysis population were ranked from the highest to lowest, in terms of contribution to total energy intake and the population intake of the nutrients of interest (protein, calcium, phosphorus, and potassium). The items contributing to 90% of the total intake were selected for inclusion in the FFQ. The representative list for energy intake is shown in Table 1. Similar lists were drawn for protein, calcium, phosphorus, and potassium intake and seven more items were added to the list derived from energy intake alone [Table 2].

The clinical, anthropometric, and laboratory parameters of the 84 study participants in the validation study are presented in Table 3. The mean age was 40 years, 62% were male, with around 2/3rd of the participants from Lucknow and neighboring towns (urban) and 1/3rd from a rural location. Out of the total, 15% of patients were Muslim, comparing to the 26% of Lucknow's population, according to the 2011 Census.^[12] The majority of the patients were from low- and middle-income groups, with an average dialysis vintage of 4 years, within a range between 13 months and 65 months. Around 14% of the patients were diabetic. The mean BMI was 20.2 kg/m².

Table 1: Ranked sources of energy intake contributing to 90% of patient energy intake						
Rank	Food item (with description)	Percent contribution	Cumulative			
1		to energy intake	percentage			
1	Cereal- <i>roti</i> (flattened wheat bread)	28.63	28.63			
2	Cereal-boiled rice	7.09	35.72			
3	Cooked vegetables-potato curry (dry)	5.16	40.88			
4	Pulses-arhar dal (pigeon pea)	3.64	44.52			
5	Cereal-aloo paratha (flattened wheat bread with potato filling)	2.82	47.34			
6	Dairy-milk (without cream)	2.78	50.12			
7	Cereal-Tehri (cooked rice preparation with vegetables)	2.11	52.23			
8	Cereal-plain paratha (flattened wheat bread)	2.10	54.33			
9	Beverages-tea	2.08	56.41			
10	Dairy-paneer and chena rasgulla (cottage cheese)	1.85	58.26			
11	Fruits -apple	1.69	59.95			
12	Cooked vegetable-bottle gourd (lauki) curry	1.51	61.46			
13	Cereal-khichdi (split yellow lentil and rice porridge)	1.44	62.90			
14	Cooked vegetable-pumpkin (kaddu) curry	1.26	64.16			
15	Snacks-sabudana kheer (sweet preparation made of tapioca pearls)	1.24	65.40			
16	Cooked vegetable-ladies finger (bhindi)	1.24	66.64			
17	Snacks-suji halwa (sweet preparation made of cream of wheat)	1.23	67.87			
18	Eggs and nonvegetarian-boiled eggs	1.10	68.97			
19	Eggs and nonvegetarian-fish curry	1.07	70.04			
20	Cereal-toasted bread	1.06	71.10			
21	Cereal-sweet daliya (bulgur wheat with milk preparation)	1.06	72.16			
22	Snacks-biscuits	1.01	73.17			
23	Cooked vegetable-peas curry	1.00	74.17			
24	Cooked vegetable-ridge gourd (tori) curry	0.92	75.09			
25	Snacks-roasted chick pea (chana)	0.87	75.95			
26	Snacks-rusk	0.86	76.82			
27	Dairy-curd	0.85	77.67			
28	Cereal-salted <i>daliya</i> (bulgur wheat with vegetables)	0.84	78.51			
29	Cooked vegetable-cauliflower curry	0.84	79.35			
30	Snacks-rice kheer (sweet preparation made of rice and milk)	0.80	80.15			
31	Cooked vegetable-pointed gourd (parwal) curry	0.79	80.94			
32	Snacks- <i>aloo bhujia</i> (fried potato snack)	0.79	81.73			
33	Snacks-moong namkeen (fried yellow lentils)	0.73	82.46			
34	Snacks-Samosa (fried pastry with potato filling)	0.73	83.19			
35	Cooked vegetable-bitter gourd curry	0.64	83.83			
36	Snacks-fried peanuts	0.56	84.39			
37	Snacks-puffed rice	0.56	84.95			
38	Eggs and nonvegetarian-chicken curry	0.56	85.51			
39	Eggs and nonvegetarian-chicken biryani (rice preparation with chicken and vegetables)	0.56	86.07			
40	Fruits-guava	0.54	86.61			
41	Fruits-gaava	0.54	87.15			
42	Cooked vegetable-fenugreek (<i>methi</i>) leaves	0.54	87.68			
42 43	Beverages- <i>lassi</i> (sweet yogurt-based drink)	0.55	88.19			
45 44	Pulses-yellow lentils (moong dal)	0.31	88.66			
44 45						
	Cooked vegetables-spinach curry	0.42	89.08			
46	Pulses-soya chunks curry	0.41	89.49			

Energy and nutrient intakes by the FFQ and the 2-day dietary recall method correlated on carrying out the Pearson correlation as well as paired t-tests, as shown in Table 4. The median correlation coefficient was 0.63, with the lowest r value being 0.55 for calcium intake and the highest being 0.73 for energy intake. The correlations

remained significant while carrying out the tests with the energy-adjusted nutrient intakes. The correlations improved on using the de-attenuation formula. For energy-adjusted intakes, de-attenuated correlation coefficients ranged from 0.35 to 0.62, and the median r value was 0.50. When the differences in nutrient intakes between the FFQ and 2-day dietary recall (for energy, protein, calcium,

Table 2: Ranked sources (upto 5-alongwith percent								
contribution) of protein, calcium, phosphorus, and								
potassium intakes								
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Rank	Protein	Calcium	Phosphorus	Potassium
1	Roti (28.75)	Milk (9.60)	Roti (32.90)	Roti (13.25)
2	Arhar	Roti (8.12)	Milk (3.91)	Potato curry
	dal (5.76)			(9.73)
3	Paneer (4.85)	Curd (4.98)	Paneer (3.79)	Arhar dal (7.78)
4	Rice (3.44)	Fish curry	Arhar dal	Raw cucumber
		(4.72)	(3.51)	(5.12)
5	Milk (3.59)	Paneer	Rice (3.15)	Aloo bhujia
		(4.03)		(4.67)

Table 3: Demographic and clinical data of the study participants in the validation study

Characteristic n=84					
Age (years)	40.0 (±16.0)				
Sex (male/female) (%)	62/22 (73.8/26.2)				
Location	Rural: 30 (35.7)				
	Urban: 54 (40.5) (64.3)				
Religion	Hindu: 72 (85.7)				
	Muslim: 12 (14.3)				
Income group (%)	High: 4 (4.8)				
	Middle: 42 (50.0)				
	Low: 38 (45.2)				
Dialysis vintage (months)	39.1 (±26.2)				
Diabetes mellitus (%)	12 (14.3)				
Dry weight (kg)	50.3 (±9.5)				
Interdialytic weight gain (kg)	2.7 (±1.0)				
Body mass index (kg/m ²)	20.2 (±3.7)				
Waist circumference (cm)	77.7 (±10.1)				
Midarm circumference of	23.6 (±3.3)				
non-fistulous upper limb (cm)					
Hemoglobin (g/dL)	9.5 (±1.9)				
Serum albumin (g/dL)	3.6 (±0.5)				
Serum calcium (mg/dL)	8.56 (±0.85)				
Serum phosphorus (mg/dL)	5.30 (±1.52)				
Serum potassium (mEq/L)	5.09 (±0.73)				
Serum intact PTH ()	324.5 (±252.8)				

phosphorus, and potassium) were plotted against the mean nutrient intakes of both the methods (Bland-Altman plots), the points were consistently biased toward a positive difference for all the nutrients [Figure 1]. The width of the limits of the agreement for energy, protein, and potassium intake by both methods was considered good as the difference between intakes was approximately equal to 1 standard deviation (SD) of the mean of the intakes. The width of the limits of the agreement for calcium intake was considered fair (approximately $2 \times SD$) and was poor for phosphorus intake (approximately $3 \times SD$).^[13] Kappa statistics showed slight agreement for calcium, phosphorus, potassium, and protein intakes by both methods and fair agreement for energy intake (κ_w 0.26) as shown in Table 5.

Discussion

This study demonstrated the design and development of an FFQ, specific to a hemodialysis population in northern India. Indian diet is heterogeneous and shows vast regional and socioeconomic variations, which precludes the use of other FFQs developed in this region, especially so in the CKD population. Hitherto, an FFQ developed for the study of diabetes and metabolic syndrome in high-income group participants from Lucknow was examined for similarities to our 154-item food list, however, it was not seen to be useful in predicting the variance of the nutrients of interest in our dialysis population.^[8] This was probably due to the inherent differences in the CKD diet and an admixture of rural and urban participants from predominantly lower and middle-income groups. Therefore, the development of this dialysis-specific FFQ resulted from a need for reliable, longitudinal dietary assessment of this nutritionally at-risk population. This interviewer-administered FFQ developed in our study could be completed in approximately 20-30 min and the interviewer (who was a trained dietician) did not report difficulties in comprehension of the individual food items and portion size estimation (with the provided visual guides for measurement).

One significant problem in computing nutrient intakes is the absence of standardized food composition tables for cooked foods in India, which leads to variations in nutrient

Table 4: Comparison of energy and nutrient intakes between the food-frequency questionnaire (FFQ) and the mean of	•
2-day dietary recall methods	

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Nutrient	FFQ	SD	2-day dietary	SD	Pearson	Р	De-attenuated	Р	Paired
	Mean		recall Mean		correlation r		correlation <i>r</i>		t test P
Energy (kcal)	1851.06	460.53	1550.60	393.13	0.734	0.000	0.792	0.000	0.000
Protein-crude (g)	60.30	15.75	48.77	14.44	0.759	0.000	0.800	0.000	0.000
Protein-energy adjusted (g)	60.45	5.01	50.11	13.73	0.445	0.003	0.480	0.001	0.000
Calcium-crude (mg)	742.62	186.99	511.11	186.29	0.547	0.000	0.548	0.000	0.000
Calcium-energy adjusted (mg)	750.61	123.70	518.59	187.81	0.312	0.044	0.350	0.039	0.000
Phosphorus crude (mg)	1548.17	404.26	1236.90	304.91	0.752	0.000	0.791	0.000	0.000
Phosphorus-energy adjusted (mg)	1557.61	126.56	1243.05	150.73	0.479	0.002	0.522	0.001	0.000
Potassium crude (mg)	3150.74	886.70	2501.85	737.78	0.634	0.000	0.658	0.000	0.000
Potassium-energy adjusted (mg)	3172.32	467.44	2517.40	537.90	0.469	0.002	0.621	0.000	0.000

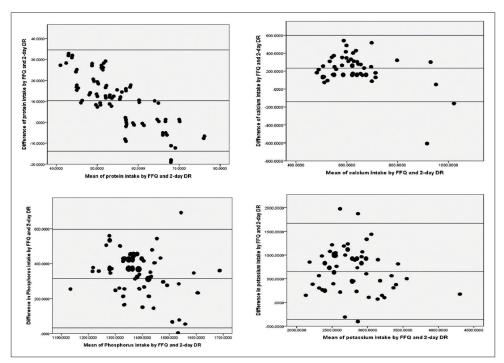


Figure 1: Bland-Altman plots assessing the validity of the food-frequency questionnaire (FFQ) against the mean of the 2-day dietary recall method

 Table 5: Testing for agreement between the FFQ and the mean of 2-day dietary recall method-cross-classification

 analyses and kappa statistics

Nutrient	Exact/adjacent quintile (%)	Gross misclassification (%)	K	95% CI
Energy	76 (90)	0 (0)	0.26	0.06-0.44
Protein	56 (67)	2 (2)	0.10	0.01-0.33
Calcium	58 (69)	5 (6)	0.14	-0.03 - 0.30
Phosphorus	56 (67)	0 (0)	0.17	-0.01 - 0.35
Potassium	56 (67)	4 (5)	0.17	0.08-0.26

estimation when using slightly different ingredients and recipes and also does not account for the loss of nutrients during cooking processes (leaching, boiling, and heating are known to cause nutrient losses to variable degrees). However, by preparation of many of these recipes in the institute's kitchen, standardization was achieved for staple foods contributing to a majority of the variance in energy and nutrient intakes. The creation of a reliable database for staple Indian cooked foods from different regions is necessary to standardize nutrient intakes across different studies.

The dialysis-specific FFQ correlated significantly with the 2-day dietary recall method and provided valid estimates of most nutrients when tested against the dietary recall method. The Bland-Altman plots showed higher estimates for energy as well as the other nutrients of interest by the FFQ method than by dietary recall. It will be necessary to further validate the FFQ using biomarkers to rule out the relative effects of recall-related under-estimation and FFQ-related over-estimation. Also, the cross-classification analysis showed that the FFQ could correctly classify patients into the exact or adjacent quintiles in 56–76% of

cases for all nutrient intakes, and gross misclassification rates were 5% or less with an average κ_w of 0.17.

The adjusted protein intake by the 2-day recall method (also by the FFQ) in the study population is 50 g/day, which corresponded to a mean protein intake of 0.97 g/kg and that protein contributed to around 13% of the cumulative energy intake, which is far lower than the recommended protein intake for patients on hemodialysis.^[14] During the initial months after hemodialysis initiation, a lag time to adapt from a protein-restricted to a protein-enriched diet may be expected. However, as all the patients in the present study were on hemodialysis for longer than 12 months, alternative explanations should be sought. Poor adherence to prescribed diets, economic constraints, caregiver burden, and lack of repeated contact with dieticians could contribute to low-protein intakes in our study participants. Mean serum albumin level was 3.6 g/dL in our study and values less than 3.7 g/dL have been associated with increased cardiovascular and all-cause mortality in previous studies.^[15] Low BMI and low midarm circumference as seen in our study are also indirectly indicative of the poor protein-energy status in these patients.

The mean daily calcium intake (energy-adjusted) in our study by dietary recall was 518 mg/day and by FFQ was 750 mg/day. However, as the mean iPTH in the population was within the target range set by KDIGO and the prevalence of secondary hyperparathyroidism was around 14%, alongwith serum calcium in the normal range, it is likely that our patients are in negative or neutral calcium balance. With regard to phosphorus intake, it is often assumed that Indian diets would not cause excessive phosphorus loads being predominantly vegetarian, low in protein and preservatives, and low in bioavailable phosphorus, however, no previous studies have confirmed or refuted these assumptions. The mean value of 1243 mg/day from the dietary recall and 1557 mg/day from the FFQ were both higher than the recommended 800-1000 mg/day to maintain neutral phosphorus balance in patients on three-per-week hemodialysis. In our center (as in a majority of Indian centers), all the patients are on a twice-weekly hemodialysis schedule, and the hyperphosphatemia seen in our patients (mean serum phosphate of 5.3 mg/dL) could be secondary to the imbalance between inadequate phosphorus removal and high phosphorus diet. A medium-sized roti, the primary staple source of energy intake among the north Indian population provides as much energy as three slices of white bread (as standardized in our kitchen), but with the additional burden of 80 mg of phosphorus content.^[16] Dals, one of the primary protein sources (even in patients who consume eggs and meat), have phosphorus to protein ratios ranging from 14 to 18 mg/g (though with lower bioavailability). This finding of a relatively high phosphorus intake in our study needs to be confirmed with larger sample size, as it has important clinical and therapeutic implications. Finally, the mean potassium intake (energy-adjusted) by the dietary recall method was 2517 mg/day (64 mEq/day) and by the FFQ it was 3172 mg/day (81 mEq/day). This is higher than the guideline recommendation of reducing potassium intake to less than 2000 mg/day or 1 mEq/kg/day.^[17] Again, the two-per-week dialysis sessions and the unaffordability of daily potassium binder therapy in our resource-limited setting, probably account for a substantial number of patients with hyperkalemia.

The strengths of the present study are the inclusion of a homogenous study population, with a reasonably long dialysis vintage and similar socioeconomic backgrounds. The interviewer-administered FFQ in the local language with visual aids to assess portion size is relatively easy for patients with low literacy to complete. Inclusion of 2 days, one predialysis and one dialysis day is important, as many patients complain of poor appetite on the day preceding hemodialysis and many others eat different foods on the dialysis day than on nondialysis days. These variations could be captured better with 2-day recall. The FFQ developed in the study provided valid estimates of intakes of energy and nutrients of interest, and though only semiquantitative, can still be used successfully to classify patients into groups based on their intakes. The study also provided important information regarding protein, calcium, phosphorus, and potassium intakes in a typical Indian dialysis population, which, to our knowledge, has never been studied before. There are important limitations to our study. We did not test our FFO for reproducibility. Testing for reproducibility helps eliminate interviewer bias and also captures seasonal variations in FFQ responses (recall bias, consumption of special foods during major festivals). However, we avoided the FFQ administration for a week following festivals. Another limitation is the absence of a nutrient database for cooked foods in India and accounting for the loss of phosphorus and potassium through cooking processes. Nevertheless, as the high intakes of these nutrients were coupled with high serum concentrations as well, they probably represent valid estimates of the true values.

Therefore, our findings of protein-poor, high phosphorus and potassium intake in the study population have important clinical implications. There is a need to design novel dietary interventions and education programs to improve the nutritional status of these socially and economically disadvantaged patients in resource-limited settings. The reinforcement of cooking techniques such as leaching and boiling and periodic counseling to foods high in phosphorus-to-protein ratio needs to be done at regular intervals.

Conclusion

This study describes the development and validation of a novel semiquantitative FFQ for use in a north Indian CKD population on hemodialysis. This FFQ can be used to provide valid estimates of energy and select nutrients of the nephrologist's interest. Using data from the dietary recall of 2 days and FFQ, it can be concluded that the study population consumes a low protein, and high phosphorus and potassium-containing diet, and further nutritional interventions should specifically target these shortcomings.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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