

EVALUATION OF THE VALIDITY FOR THE NOVEL CKD ASSESSMENT CHECK-LIST BY THE FRONTIER OF RENAL OUTCOME MODIFICATIONS IN JAPAN (FROM-J) STUDY

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abstract

INTRODUCTION AND AIMS: The number of end-stage kidney disease (ESKD) patients worldwide shows an increasing trend, presenting a growing social and economic concern. In Japan, a strategic study was carried out to improve the management of chronic kidney disease (CKD) and reduce the number of patients needing to initiate renal replacement therapy due to ESKD; this study was termed the Frontier of Renal Outcome Modifications in Japan (FROM-J). This study had an open cluster randomized design with 2 intervention groups: group A (weak intervention) and group B (strong intervention). The patients in group B were not only instructed in the same way but also received consultations by dietitians, visits at their homes by doctors, and support from an information technology-based system designed to help achieve the goals of CKD treatment and consultation support centers. The dietitians provided patients with guidance regarding not only their diet, but also their lifestyle habits including medication and smoking. In total, 1184 eligible patients were registered in group B and 315 dietitians participated in the study. For the controlled trial of an educational intervention, the method must be standardized, including the instructions given to patients. A large number of patients and dietitians participated in this study; therefore, the check-list was prepared to facilitate the uniform application of the intervention. The aim of this study is to evaluate the validity for the novel CKD evaluation check-list by 'FROM-J' study.

METHODS: We evaluated the agreement degree between dietitians in relation to an instruction item extracted from the novel CKD evaluation check-list. Moreover, we evaluated the concordance between dietitians and we assessed the accuracy of the protein and salt intake estimates made by dietitians who only had access to patients' food diaries and verbal reports through comparison with assessments made by an independent dietitian who additionally had access to patients' meal photographs and urine collections.

RESULTS: The most frequent instruction was blood pressure control (46%), the 2nd was BMI control (28%), the 3rd was potassium control, respectively. The instruction item corresponded about 94% for the first time, 74% for the second time, and 84% in total between dietitians. The dietitians evaluated salt intake into three groups, I: <6(g);II: 6-12(g);III: 12(g)≤, respectively. The concordance rates between dietitians were 77.1%, and kappa coefficient was 0.633. The dietitians also evaluated protein intake into three groups, I: <0.8(g/kg);II: 0.8-1.2(g/kg);III: 1.2(g/kg)≤, respectively. The concordance rates between dietitians were 80.8%, and kappa coefficient was 0.613. A strong correlation exists between dietitian's assessment and objective evaluation. The concordance rates between the dietitians' estimates and the independent dietitian's objective assessment were 78.5% and 45.1%, and Cohen's κ coefficients were 0.616 and 0.311 for salt and protein intakes, respectively. The estimates and objective assessments were strongly correlated for salt intake, but more weakly correlated for protein intake.

CONCLUSIONS: We concluded that the checklist was appropriate for the evaluation of CKD patients. We hope that it will be useful for the instruction of CKD patients more widely in the future.

Aims

The validity of this novel checklist-guided educational intervention method for CKD patients had not been clarified until now. The objectives of this study were twofold;

- 1) To determine the degree of concordance among dietitians in the instructions given to patients.
- 2) To evaluate the accuracy of the evaluations of protein and salt intakes made by the dietitians based on patients' food diaries and verbal reports through comparison with the assessments made by an independent dietitian who additionally had access to patients' meal photography and urine collection.

Materials and methods

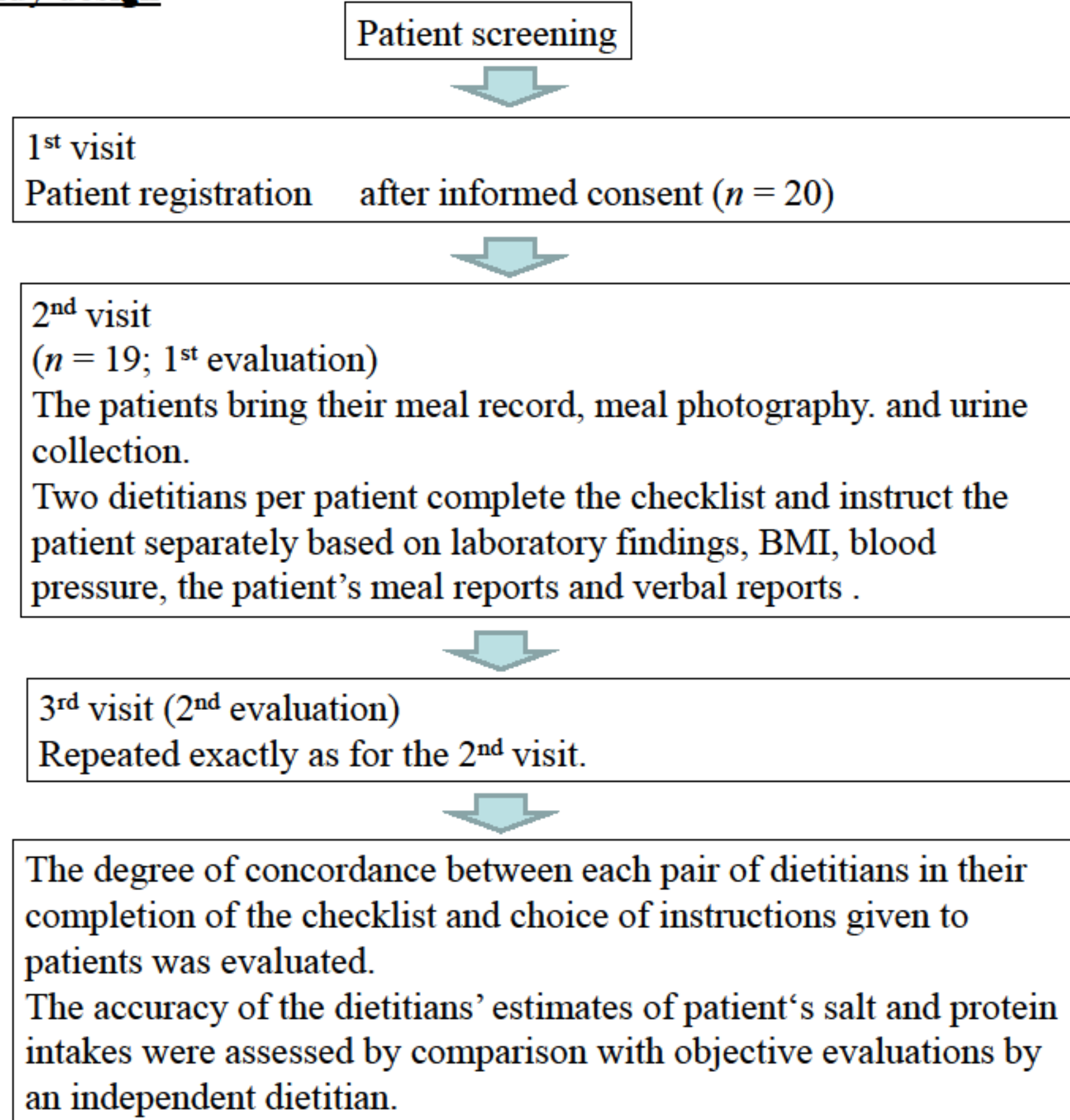
Checklist in this study (Ref.1,2)

A novel CKD assessment check-list used in the Frontier of Renal Outcome Modifications in Japan (FROM-J) study

MEDICATION ADHERENCE
 Taking medication accurately Without prescription
 Number of times forgetting to take medicine per week once two or three times four or five times

Education content	Patient's results and score classification	Note
BMI control	BMI (kg/m ²) 18.5 → 25 → 28 → 35 ← 4 ← 3 ← 2 ← 1 → 0	-To "K" energy control manual -For patients 65 years or older, measurements of systolic blood pressure is less than 135 mmHg in the examination room -score 1 -No data -To the algorithm of BP education
Blood pressure control	BP (mmHg) 160/110 → 150/100 → 140/90 → 130/80 ← 4 ← 3 ← 2 ← 1 → 0	-To the algorithm of BP education
Glycemic control	HbA1c (%) 10.5 → 7.9 → 7.4 → 6.9 ← 4 ← 3 ← 2 ← 1 → 0	-To the algorithm of glycemic control education -No data
Serum lipid control	LDL-C (mg/dl) 200 → 180 → 160 → 140 → 120 ← 4 ← 3 ← 2 ← 1 → 0	-Without calculations (postprandial blood sampling) -To the algorithm of serum lipid control education
Salt intake	Salt intake (g/day) 12 → 6 → 3 ← 4 ← 3 ← 2 ← 1 → 0	-Without food record -To "K" low-salt diet manual
Smoking habit	Number of cigarettes smoked per day 30 → 20 → 10 → 1 → 0 ← 4 ← 3 ← 2 ← 1 → 0	-To the algorithm of smoking cessation education -No data
Potassium control	K (mEq/d) 6.0 → 5.5 → 5.0 → 4.5 ← 4 ← 3 ← 2 ← 1 → 0	-To the algorithm of potassium control education -No ratings, because CKD stage is G1 or G2
CKD stage G3 and over	Protein intake (g/kg/day) 1.2 → 0.8 → 0.8 ← 4 ← 3 ← 2 ← 1 → 0	-Without food record -To "K" low-protein diet manual

Study design



Statistical analysis

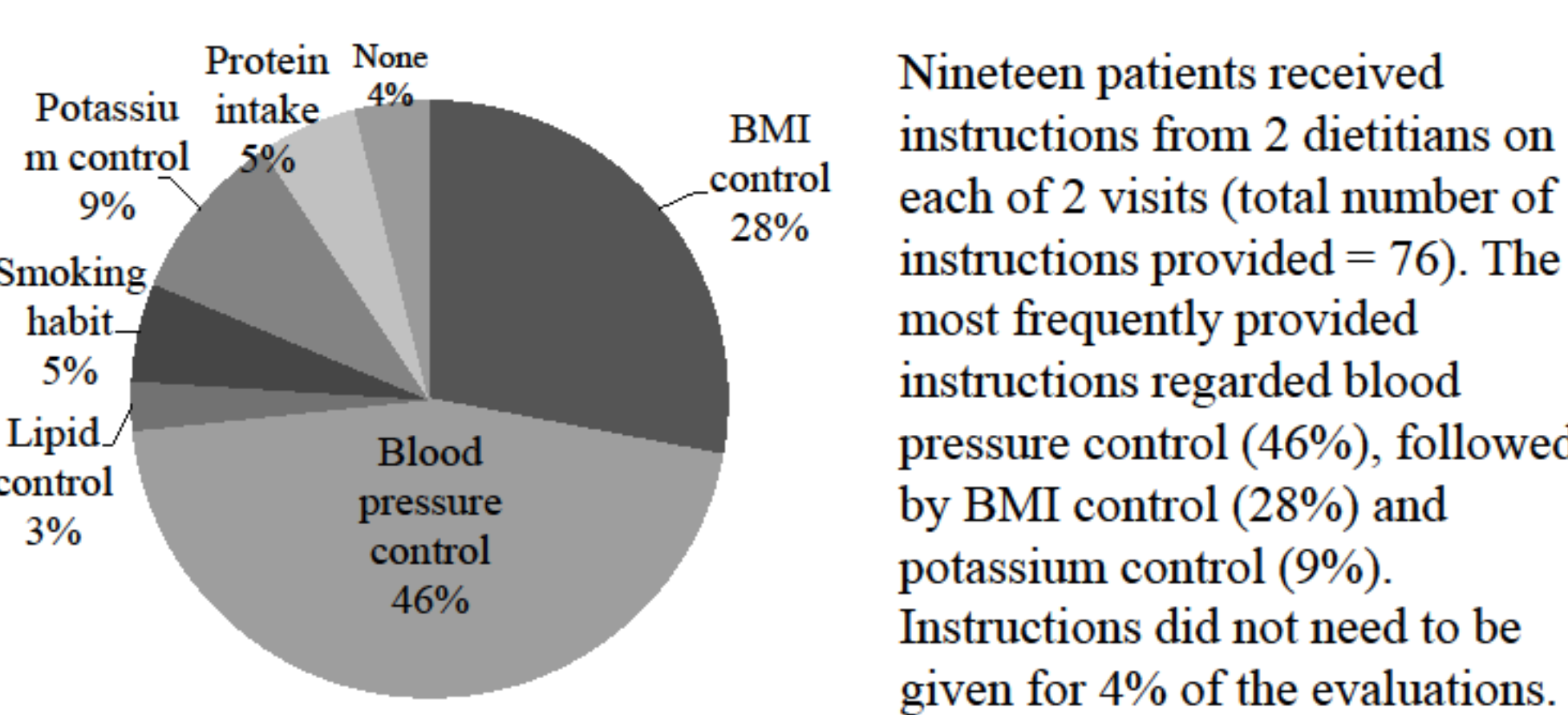
Patients' salt and protein intakes were each categorized into 3 groups in this study. During data analysis, the assessments of patients performed by the dietitians were first evaluated using the exact degree of concordance and Cohen's κ coefficient to determine the agreement for categorical variables between the evaluations by the dietitians involved in the study and the independent dietitian. Weighted Cohen's κ coefficient was also calculated to consider partial agreement. Next, a single linear regression analysis was performed to determine the relationships among the continuous variables as estimated by the dietitians involved in the study and objectively assessed by an independent dietitian. All statistical analyses were performed using the Statistical Package for R, version 3.2.0 (R Foundation for Statistical Computing, Vienna, Austria).

Results

The baseline characteristics of patients in this study

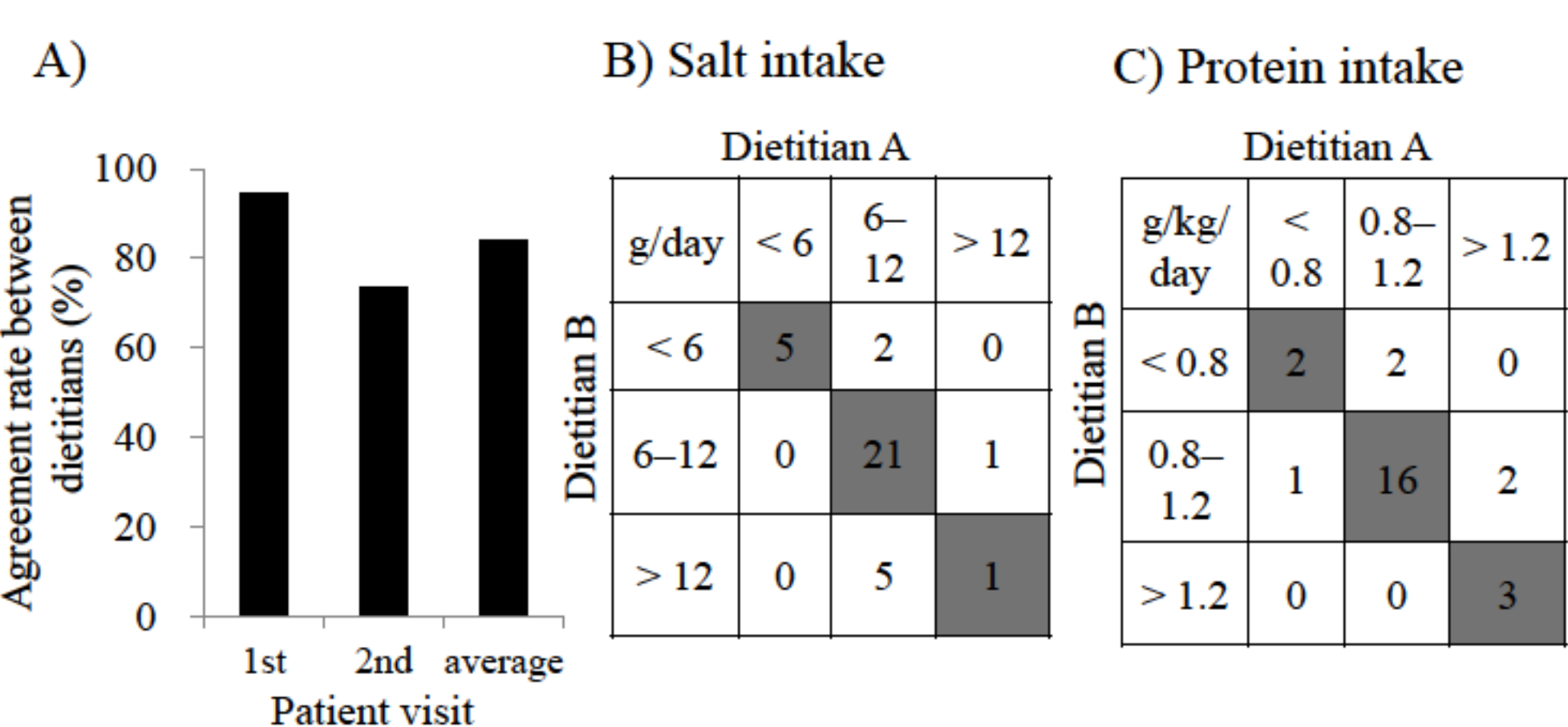
	19	Laboratory results
Total number	19	TP (g/dl) 7.1 ± 0.4
Age (years)	65.1 ± 9.3	Alb (g/dl) 4.1 ± 0.3
Female gender (%)	52.6	Na (mEq/l) 142 ± 1.7
BMI (kg/m ²)	24.0 ± 4.2	Cl (mEq/l) 105 ± 2.7
Systolic blood pressure (mmHg)	131.7 ± 12.5	K (mEq/l) 4.6 ± 0.7
Diastolic blood pressure (mmHg)	71.8 ± 7.2	BUN (mg/dl) 30.2 ± 12.2
Smokers (%)	10.5	CRE (mg/dl) 1.78 ± 0.9
Urine collection		eGFR (ml/min) 35.4 ± 19.8
UV (ml/day)	1995 ± 681	UA (mg/dl) 6.8 ± 1.7
NaCl (g/day)	7.7 ± 3.0	CHO (mg/dl) 184 ± 20
UP (g/day)	1.0 ± 1.0	TG (mg/dl) 138 ± 54
UN (mg/dl)	377 ± 115	HDL-C (mg/dl) 54.5 ± 18.5
CRE (mg/dl)	56.0 ± 21.4	BS (mg/dl) 121 ± 30
		HbA1c (%) 6.2 ± 0.6
		Hb (g/dl) 12.4 ± 1.6

Pie chart showing the frequency at which lifestyle instructions regarding each topic were given based on the evaluation of CKD patients by dietitians using the FROM-J checklist (Fig.1)



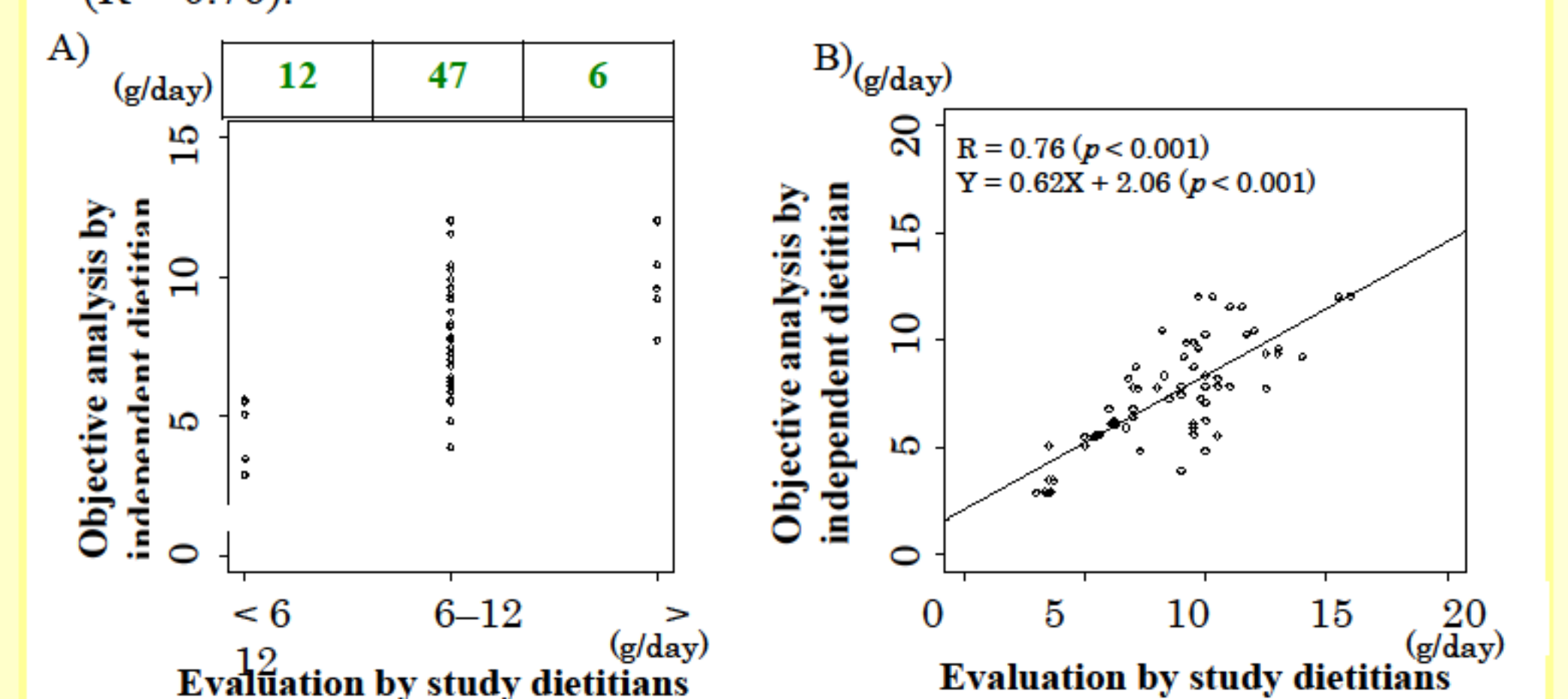
The concordance rates between dietitians for their assessments of salt and protein intakes (Fig.2)

- A) The dietitians selected an instruction item based on their assessment using the checklist. The choice of items corresponded between the dietitians at a rate of 94% for the patients' first visits, 74% for their second visits, and 84% on average.
- B) The dietitians categorized patients' salt intake into 3 groups (< 6, 6-12, and > 12 g/day). In total, 35 assessments were made. The concordance rate between dietitians was 77.1% and Cohen's κ coefficient was 0.633.
- C) The dietitians categorized patients' protein intake into 3 groups (< 0.8, 0.8-1.2, and > 1.2 g/kg/day). The total number was 26. The coincidence ratio was 80.8% between dietitians and Cohen's κ coefficient was 0.613.



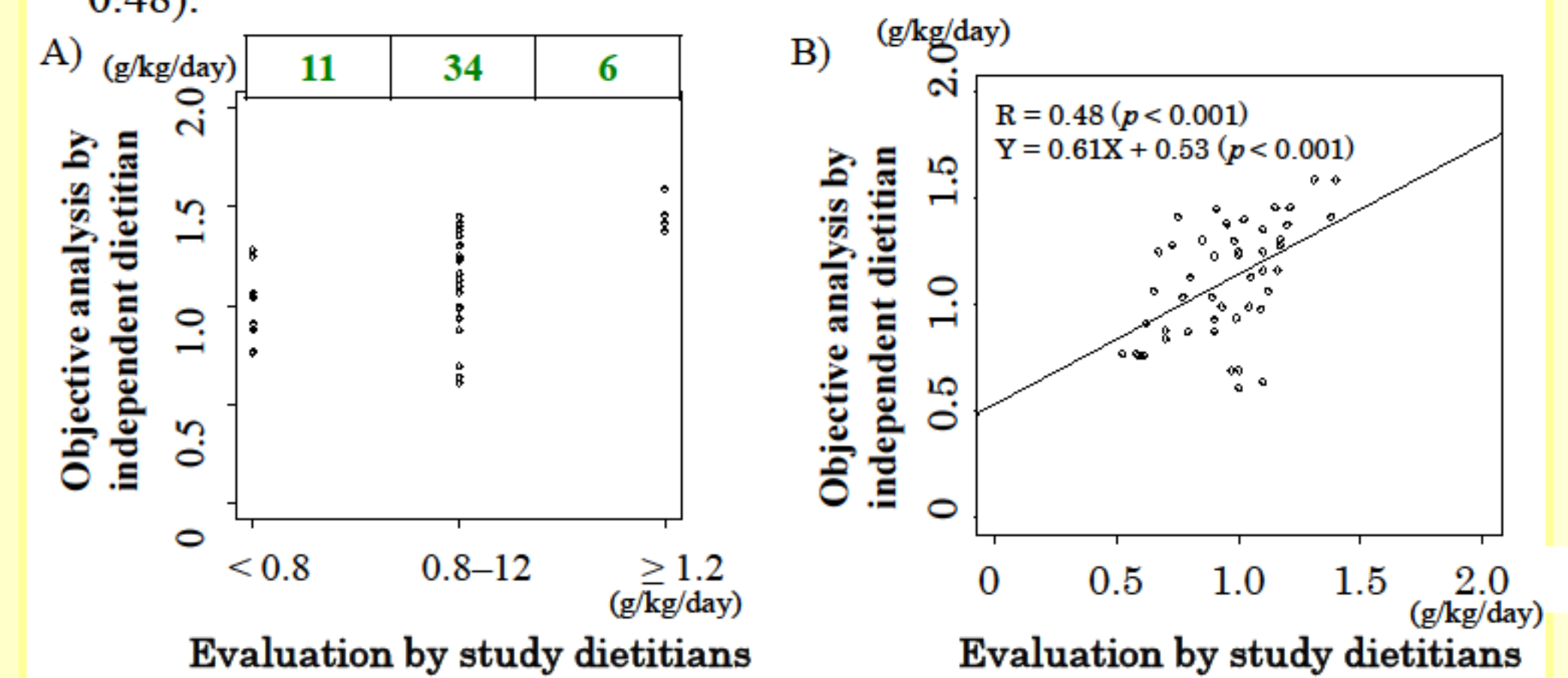
Assessment of the accuracy of the dietitians' estimates of patients' salt intake (Fig.3)

The x-axis of each panel shows the salt intake of each patient as estimated by the study dietitians, who only had access to patients' food diaries, and the y-axis shows salt intake as determined by an independent dietitian, who additionally had access to patients' urine samples and meal photographs. A) The dietitians categorized patients' salt intake into 3 groups (< 6, 6-12, and > 12 g/day). The vertical line shows the objective evaluations by the independent dietitian. In total, 65 assessments were performed. The coincidence rate was 78.5% and Cohen's κ coefficient was 0.616. B) The relationship between the estimates of salt intake by the dietitians involved in the study and the objective evaluations by the independent dietitian. The estimates and objective evaluations were strongly correlated (R = 0.76).



Assessment of the accuracy of the dietitians' estimates of protein intake (Fig.4)

The x-axis of each panel shows the protein intake of each patient as estimated by the study dietitians, who only had access to patients' food diaries, and the y-axis shows protein intake as determined by an independent dietitian, who additionally had access to patients' urine samples and meal photographs. A) The dietitians categorized patients' protein intake into 3 groups (< 0.8, 0.8-1.2, and > 1.2 g/kg/day). The vertical line shows the objective evaluations by the independent dietitian. In total, 51 assessments were performed. The coincidence rate was 45.1% and Cohen's κ coefficient was 0.311. B) The relationship between the estimates of protein intake by the dietitians involved in the study and the objective evaluations by the independent dietitian. The estimates and objective evaluations were correlated (R = 0.48).



Discussion

Lifestyle modification is an important method for the control of CKD, and early intervention is critical for preventing the progression of CKD to more serious conditions including cardiovascular complications, which can result in death. The provision of instructions aimed at improving diet and lifestyle factors related to obesity, salt intake, and potassium intake was prioritized. In this study, items of instruction that were frequently provided to patients by dietitians based on their assessment using the checklist included those regarding the control of high blood pressure and obesity (Fig. 2). However, it is not clear whether the dietitians identified the most important risk factor for each patient. The results of the FROM-J study showed that the average eGFR deterioration speed of all patients showed a tendency towards being reduced, and a significant improvement was observed in CDK stage 3 patients (Ref.3). We considered that the selected instruction items were mostly appropriate, and the effectiveness of the intervention using this method should become clear soon.

We used a simple method to enable dietitians to complete the checklist in a short time. Therefore, we classified salt intake into 3 categories (< 6, 6-12, and > 12 g/day); dietitians assigned each patient to these categories based on their meal reports and verbal discussion. A salt intake of < 6 g/day is the target value specified by CKD medical treatment guidelines and > 12 g/day is considered an excessive intake. There was a high degree of concordance between dietitians in their evaluations of patients' salt intakes, which supported the appropriateness of the 3 categories for salt intake used in this checklist (Fig. 3). The strong correlation between dietitians' estimates of patients' salt intake and the independent dietitian's objective evaluations suggests that this checklist may represent a useful assessment method for dietitians.

Conclusion

We concluded that the provision of lifestyle modification instructions to CKD patients based on their assessment by dietitians using the checklist method was appropriate in this study. We hope that it will be used for the evaluation and instruction of CKD patients more widely in the future.

Conflict of interest
 The authors have declared that no conflict of interest exists.
Support and Financial Disclosure Declaration and Acknowledgements
 This study was supported in part by a Grant-in-Aid for Research on Advanced Chronic Kidney Disease (REACH-J), Practical Research Project for Renal Diseases from Japan Agency for Medical Research and Development,AMED. This study was also supported in part by a grant for a strategic outcome study project from the Ministry of Health, Labour and Welfare of Japan.
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