

# Development of questionnaire on perception of patients with diabetic nephropathy

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## Abstract

**Objective:** As diabetes is the main reason for dialysis, it is important to help patients prevent or delay the need for dialysis treatment. Previous studies have suggested that the absence of symptoms in diabetic nephropathy influences the patient's perception of the condition and attitude toward treatment. This study was performed to develop and examine the reliability and validity of a questionnaire on the perception of patients with diabetic nephropathy.

**Method:** We employed 10 categories and 24 subcategories to explain the perception of patients with diabetic nephropathy at the time of diagnosis obtained from previous studies. We distributed a self-administered questionnaire containing 28 items (5-point Likert Scale) covering basic attributes.

**Subjects:** The study population consisted of 175 patients with diabetic nephropathy in the second and third stages undergoing treatment at six hospitals, including guidance designed to prevent the need for dialysis. Informed consent was obtained from all patients.

**Results:** We developed a questionnaire on the perception of patients with diabetic nephropathy based on four factors and 20 items with a contribution ratio of 50.56%. Cronbach's alpha coefficient was 0.594 – 0.768, indicating the reliability of the questionnaire. The construct discriminative and concurrent validities, and comparison with the uncertainly theory of Mishel (1988) indicated the validity of the questionnaire. The factors were as follows: Factor 1, "Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future"; Factor 2, "Becoming calm after accepting my condition"; Factor 3, "Slight shock when diagnosed with nephropathy"; and Factor 4, "Feeling helpless about diabetic nephropathy."

## KEY WORDS

Diabetic nephropathy, Questionnaire, Perception, Complication, Nursing

## I. Introduction

The recent top cause for dialysis is diabetic nephropathy. The population of patients requiring dialysis due to diabetic nephropathy exceeds 100,000<sup>1)</sup>. Dialysis may not only cause lowering of QOL of patients, but also lead to financial strain in healthcare. This highlights the need for preventive measures against diabetic nephropathy and the need for dialysis.

In 2012, diabetic dialysis prevention guidance & a management fee system were initiated as preventive measures. This has promoted implementation of diabetic

dialysis prevention guidance in a number of hospitals. In order to prevent the need for dialysis and slow the progress of diabetic nephropathy, it is necessary to significantly change the priority from blood-sugar control to kidney protection as deterioration of renal function advances<sup>2)</sup>.

Diabetic nephropathy patients often, however, do not notice symptoms until renal functions have deteriorated significantly<sup>3)</sup>. This makes it difficult for diabetic nephropathy patients to perceive the mild deterioration of renal function as physical change. Previous studies

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have reported that patients in the early stage of diabetic nephropathy understand their condition, but tend to forget about it due to the absence of symptoms, which in turn results in their changing or abandoning treatment<sup>4)</sup>. To identify the mechanism, it is necessary to clarify patient perception and awareness of physical conditions. In a previous study, we attempted to clarify patient perception of their physical condition utilizing a qualitative method. Patients exhibited a tendency to consider their disease history and lifestyle, including serious diseases such as diabetes, diabetic nephropathy and other complications, physical conditions through aging, and their experience to arrive at the desirable behavior for medical treatment<sup>5)</sup>. This suggested that patients with fewer symptoms may recognize the fact that they have nephropathy through diagnosis rather than the physical conditions caused by it. This also showed similarity with a study<sup>6)</sup> reporting that a patient without symptoms must become conscious of “the body as a result of a lifestyle” before they focus on lifestyle and an awareness of habits. These findings prompted the conclusion that patient awareness of physical condition is useful in encouraging them to follow appropriate treatment. In addition, results suggested that guidance based on patient perception of physical condition may be useful in dialysis prevention guidance for individuals with fewer symptoms. Therefore, in this study, we first created the questionnaire on diabetic nephropathy patient perception, and examined its reliability and validity.

## II. Definition of terms

Perception of physical condition here means at the time of diagnosis the diabetic nephropathy patient awareness of physical condition and lifestyle in relation to diabetes and diabetic nephropathy through their past, present, and future experience.

## III. Study methods

### I. Creation of the questionnaire on diabetic nephropathy patient perception (Table 1)

In order to create the questionnaire on diabetic nephropathy patient perception, we employed 10 categories and 24 sub-categories extracted from the author’s previous study on “Self-perception of physical state in patients in the initial stage of diabetic nephropathy when diagnosed.”<sup>5)</sup>. Relationship between the items in the previous study and our draft are shown in Table

1. The results revealed patient recognition of physical condition at diagnosis. For recognition, we extracted the following categories; [patient realization of the difference between the diagnosis and physical state] , [there is no cure for diabetes] , [feeling physically able to handle self-management] , [patients do not want to acknowledge that they have nephropathy] , [patients see nephropathy as an abstraction] , [patients understand the concept of complications based on their knowledge] , [patients hope they can maintain their current state] et al.

Merle H. Mishel<sup>7)</sup> defined uncertainty in illness as the inability to determine the meaning of illness-related events occurring when the decision maker is unable to assign definite value to objects or events, or is unable to accurately predict outcomes. The theory of uncertainty in illness states that patient recognition of uncertainty in illness and their efforts to control it lead to strength in dealing with disease and treatment. Results of the previous study successfully described patients’ abstract recognition of uncertainty in illness. I thought it is important for patients to become aware of the abstract recognition and face the disease to prevent serious diabetic nephropathy. Therefore, we used the results of the previous study<sup>5)</sup> as a theoretical framework for the questionnaire.

One questionnaire item was chosen from a sub-category of the previous study results. In order to provide questions that were easy to answer, some questionnaire items and names were applied from the categories of the previous study. Sub-categories with complex meanings were divided into two questionnaire items. We added descriptions for the items and expressions that were difficult to understand and created the questionnaire items in cooperation with researchers that had experience in clinical nursing care. Furthermore, we asked two patients diagnosed with diabetic nephropathy on medication to examine the face validity of the questionnaire prior to this study. As a result, some expressions in questionnaire items and the order of the answers were revised. In the end, we chose 28 items in the draft. A five-point Likert scale was provided for the 28 questionnaire items. The five response options were (1) strongly disagree, (2) disagree, (3) neither agree nor disagree, (4) agree, (5) strongly agree.

## 2. Reliability and validity

### 1) Subjects

Subjects of this study are type II diabetes patients aged

below 75 years diagnosed with second- and third-phase diabetic nephropathy. Patients who were unable to answer the self-administered questionnaire were excluded from the subjects.

Subject facilities of this study were six hospitals providing dialysis prevention guidance in Prefecture I that agreed to participation in the survey. A breakdown of the number of hospital beds is 200 – 300 beds (2 facilities) , 300 – 400 beds (3 facilities) , and 800 beds and more (1 facility) . Three of these facilities employed nurses certified in diabetes nursing.

**2) Questionnaire items**

**(1) Basic attribute**

We included the following basic attributes in the questionnaire items; sex, age, history of diabetes, history of

diabetic nephropathy, awareness of the stage of diabetic nephropathy, hospitalization for diabetes education, participation in diabetes education, history of complications (neuropathy, retinopathy, heart disease, cerebrovascular disease, mortification, cancer) , diabetes treatment, HbA1c (recent value) .

**(2) Draft of the questionnaire (28 items)**

**3) Data collection method**

Data was collected from a self-administered questionnaire. We explained the purpose of this study to subjects and asked for their cooperation at hospitals that agreed to participation in this study, and delivered a participation request form and questionnaire to each subject. Data was collected from October 2013 to June 2014.

Table 1 Questionnaire on perception of patients with diabetic nephropathy (draft)

Item Number in the Original Draft	Category in the Previous Study	Item Number in the Final Draft	Questionnaire on perception of patients with diabetic nephropathy (draft)
1	[Patient realization of the difference between the diagnosis and physical state] "I did not imagine that I would be diagnosed with a kidney disease." "I do not know what condition a nephropathic kidney is in."	1	I was very surprised to have been diagnosed with diabetic nephropathy.
2		2	I felt surprised when I was diagnosed with a kidney problem because I had no symptoms.
3		3	I was diagnosed with diabetic nephropathy, but I am not sure what that means for my kidney.
4	[Feeling physically able to handle self-management] "I will live long although I'm sick." "My body has with many complications." "My body is suffering from a cancer." "I do everything I can for my body."	4	I am old, so I am ready to accept that my kidney is bad.
5		6	I accept that I have nephropathy because I already have complications.
6		7	I have had health problems before, so I accept that I have nephropathy.
7		8	I have had life-threatening illnesses before, so I accept that I have nephropathy.
8		9	I have done what I can.
9		10	I am happy that I have been able to manage my condition until now.
10		11	I realize that I am in poor health.
11	[Patient anxiety about life and a physical state that requires life-long dialysis] "I do not want a body that requires dialysis." "It is scary to need dialysis." "I do not want to trouble my family."	12	I am worried that I might need dialysis in the near future.
12		14	I am ready to accept the need for dialysis in the near future.
13		15	I do not want to become a dialysis patient and bother people around me.
14	[There is no cure for diabetes.] "This will not be cured." "This will cause complications if left untreated."	16	I am afraid of diabetes.
15		17	I am afraid of diabetes because I may develop complications if it is not treated appropriately.
16		18	I think diabetes is incurable.
17	[Patients do not want to acknowledge that they have nephropathy.] "I only think about one thing now." "I will worry about it when I need dialysis."	19	I focus on improving my blood-sugar level.
18		13	I will worry about it when I need dialysis.
19		23	I think it is impossible to improve my condition.
20	[Patients see nephropathy as an abstraction.] "I try not to worry about having nephropathy seriously." "I have nephropathy, but not from diabetes."	20	I am trying not to think seriously about my condition.
21	[Patients accept the situation only if their physical state will not worsen.] "I want to prevent worsening if possible." "It is fine if my current lifestyle is not affected." "I cannot make it any better."	21	I hope that my diabetic nephropathy will not worsen beyond its current state.
22		22	I hope that I can maintain my current lifestyle as long as possible.
23	[Patients understand the concept of diabetes and its complications based on their knowledge.] "This is an aggravation of diabetes, and its progression can be stopped." "Diabetes is a disease that has complications."	24	I believe that I can prevent my diabetes from worsening.
24		5	I think my nephropathy was caused by diabetes.
25	[Patients understand their actual physical state, including the initial stage of nephropathy.] "I understand that it is early period of kidney disease to see the inspection numerical value of my kidney." "I still think it is far from a problem that requires dialysis."	25	I saw the test results and know how bad my kidney is.
26		26	I have nephropathy, but I will not need dialysis soon.
27	[Patients hope they can maintain their current state.] "I want to be cured if possible." "I want to maintain my present state, which is not bad."	27	I want to cure my diabetic nephropathy.
28		28	I want to prevent the nephropathy from worsening.

#### 4) Data analysis

We applied a statistical method to analyze data to create the questionnaire on perception of patients with diabetic nephropathy. We set significance at  $p < 0.05$  and used SPSS Statistics 21.0 for all data analysis. Data was presented as the mean  $\pm$  standard deviation for continuous variable.

##### (1) Item analysis

We confirmed ceiling and floor effects. We also acquired Item-total correlation coefficient to confirm the reliability of each item.

##### (2) Extraction and naming of factors

We applied exploratory factor analysis utilizing promax rotation and principal factor method.

Utilizing the factor analysis results, we named subscales according to the characteristics of each item.

##### (3) Examination of reliability

We acquired Cronbach's  $\alpha$  coefficient for each factor to confirm the reliability of the internal consistency.

##### (4) Examination of validity

###### a. Examination of construct validity

We compared factor analysis results with the original categories used to create the draft of the questionnaire.

###### b. Examination of discriminant validity

We confirmed differences among the scores of each factor in the questionnaire utilizing the Mann-Whitney U test according to the basic attributes; namely, history of major complications other than nephropathy (neuropathy and retinopathy) and need for insulin injections. And we also clarified differences among the scores of each factor in the questionnaire by the level of HbA1c values utilizing Kruskal Wallis test.

#### 3. Ethical consideration

We explained the purpose and meaning of this study to individual participants both orally and in writing. We also explained that participation in this study was voluntary, and other ethical considerations such as personal information protection and the limitation of use of said personal information within this study. Return of the questionnaire responses was considered consent for participation in this study. This study was also approved by the Kanazawa University Ethical Committee (Approval No. 459).

#### IV. Results

The number of collected questionnaire responses was 222 (response rate: 68.1%). We excluded responses from

subjects that did not answer all items of the questionnaire, those who responded that their history of diabetic nephropathy was longer than their history of diabetes, and those who did not know their HbA1c values. The final number of subjects for analysis was 175 (valid response rate: 54.0%).

##### 1. Basic subject attributes (Table 2)

Subjects of this study were 121 males (69.1%) and 54 females (30.9%). Mean age of the subjects was  $63.4 \pm 9.0$  years. Mean history of diabetes was  $14.1 \pm 9.3$ , and the mean history of diabetic nephropathy was  $2.4 \pm 4.5$ . Among those with complications, 62 subjects had retinopathy (35.4%), which was the largest. Subjects who used insulin injections were 66 (37.7%). The number of subjects whose level of HbA1c was from 6% and above to less than 7% was 71 (40.6%), which was the largest. Details of other basic attributes are shown in Table 2.

##### 2. Creation of questionnaire on perception of patients with diabetic nephropathy (Table 3)

###### 1) Results of item analysis

None of the 28 items in the draft showed ceiling and floor effects. Although the item-total correlation coefficient should be 3.0 or greater, item No.23 was 0.02, item No.26 was 0.09, item No.20 was 0.10, item No.24 was 0.13, item No.4 was -0.24, and item No.22 was 0.25, all of which were lower than the appropriate level. However, those items, which were extracted from the results of the previous qualitative study<sup>5)</sup> when we made the original draft, were considered to be appropriate as the construct; therefore, we decided to use the items for the analysis.

###### 2) Results and naming of exploratory factor analysis

We applied the principal factor method and promax rotation for factor analysis. Kaiser-Meyer-Olkin measure of sampling adequacy was 0.71, which showed that the application of factor analysis was appropriate. Cumulative contribution ratio before rotation was 50.2%. We checked the scree plot and chose factors whose initial fixed value was 1,000 or more. As a result, four factors were extracted. We conducted factor analysis until factor load of all the items reached 0.4 or more, and eight items were excluded. Finally, we chose four factors and 20 items used for the questionnaire on perception of patients with diabetic nephropathy (Table 3). Contribution ratio of four factors was 50.56%.

Factor 1 included "I am afraid of diabetes," "I am

Table 2 Basic attributes of subjects

n=175

Item	Mean value ± Standard deviation		
Age	63.4±9.0		
History of diabetes (years)	14.1±9.3		
History of diabetic nephropathy (years)	2.4 ±4.5		
Item	Group	Score	(%)
Sex	Male	121	(69.1)
	Female	54	(30.9)
Awareness of the stage of diabetic nephropathy	Stage 2	35	(20.0)
	Stage 3	28	(16.0)
	Unknown	112	(64.0)
Hospitalization for diabetes education	Yes	113	(64.6)
	No	61	(34.9)
	Unknown	1	(0.6)
Participation in diabetes education	Yes	115	(65.7)
	No	58	(33.1)
	Unknown	2	(1.1)
History of complications (multiple answers possible)	Neurosis	37	(21.1)
	Retinal	62	(35.4)
	Heart disease	24	(13.7)
	Vascular brain disease	16	(9.1)
	Mortification	4	(2.3)
	Cancer	13	(7.4)
Diabetes treatment (multiple answers possible)	Dietetic therapy	121	(69.1)
	Exercise therapy	75	(42.9)
	Internal medicine	135	(77.1)
	Insulin injections	66	(37.7)
HbA1c (recent value)	Less than 6%	10	(5.7)
	6% and greater and less than 7%	71	(40.6)
	7% and greater and less than 8%	58	(33.1)
	8% and greater	36	(20.6)

Table 3 Questionnaire on perception of patients with diabetic nephropathy

Item	1	2	3	4	
<b>Factor 1: Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future</b>					
• I am afraid of diabetes because I may develop complications if it is not treated appropriately.	<b>.805</b>	.017	.046	.039	
• I am afraid of diabetes.	<b>.733</b>	-.033	.020	.024	
• I want to cure my diabetic nephropathy.	<b>.555</b>	.075	.050	-.072	
• I am worried that I might need dialysis in the near future.	<b>.524</b>	.201	.086	.138	
• I hope that my diabetic nephropathy will not worsen beyond its current state.	<b>.483</b>	-.046	-.024	-.286	
• I believe that I can prevent my diabetes from worsening.	<b>.472</b>	-.007	-.011	.067	
• I hope that I can maintain my current lifestyle as long as possible.	<b>.450</b>	-.204	-.060	.060	
• I do not want to become a dialysis patient and bother people around me.	<b>.442</b>	.133	-.004	.006	
<b>Factor 2: Becoming calm after accepting my condition</b>					
• I have had life-threatening illness before, so I accept that I have nephropathy.	-.175	<b>.760</b>	.036	-.188	
• I have had health problems before, so I accept that I have nephropathy.	-.033	<b>.736</b>	.029	.026	
• I am happy that I have been able to manage my condition until now.	.109	<b>.509</b>	-.066	-.059	
• I accept that I have nephropathy because I already have complications.	.171	<b>.443</b>	-.037	.143	
• I am ready to accept the need for dialysis in the near future.	.122	<b>.420</b>	-.093	.281	
<b>Factor 3: Slight shock when I was diagnosed with nephropathy.</b>					
• I felt surprised when I was diagnosed with a kidney problem because I had no symptoms.	-.057	-.043	<b>.975</b>	.007	
• I was very surprised to have been diagnosed with diabetic nephropathy.	.187	.005	<b>.535</b>	-.127	
• I was diagnosed with diabetic nephropathy, but I am not sure what that means for my kidney.	.005	-.023	<b>.485</b>	.142	
<b>Factor 4: Feeling helpless about diabetic nephropathy.</b>					
• I think diabetes is incurable.	.203	-.195	-.004	<b>.646</b>	
• I am always prepared for the time I will require dialysis.	-.081	.214	.036	<b>.565</b>	
• I want to prevent the nephropathy from worsening.	.004	.007	-.002	<b>.512</b>	
• I think it is impossible to improve my condition.	-.410	-.031	.058	<b>.464</b>	
	Contribution rate	19.137	14.587	8.770	8.066
	Cumulative contribution rate	19.137	33.725	42.495	50.561
	Factor correlation coefficient	1	2	3	4
		1.000	.042	.236	.077
			1.000	.115	.343
				1.000	.122
					1.000
	Cronbach's α coefficient	.768	.708	.688	.594



worried that I might need dialysis in the near future,” “I do not want to become a dialysis patient and bother people around me,” “I believe that I can prevent my diabetes from worsening,” and “I hope that I can maintain my current lifestyle as long as possible.” These describe anxiety and awareness about the changes in physical conditions and lifestyles; therefore, we named this factor “Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future.”

Factor 2 included “I have had life-threatening illness before, so I accept that I have nephropathy” and “I am happy that I have been able to manage my condition until now.” These describe the attitude of patients that review their experience and calmly accept their condition; therefore, we named this factor “Becoming calm after accepting my condition.”

Factor 3 included “I felt surprised when I was diagnosed with a kidney problem because I had no symptoms” and “I was diagnosed with diabetic nephropathy, but I am not sure what that means for my kidney.” Those describe the patient anxiety about their physical conditions through the diagnosis as nephropathy; therefore, we named this factor “Slight shock when I was diagnosed with nephropathy.”

Factor 4 included “I think diabetes is incurable” and “I think it is impossible to improve my condition.” Those describe that patients’ think of diabetes and diabetic nephropathy as incurable diseases; therefore, we named this factor “Feeling helpless about diabetic nephropathy.”

Factor 1 “Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future” and Factor 3 “Slight shock when I was diagnosed with nephropathy” showed a weak positive correlation ( $r=0.234$ ), and Factor 2 “Becoming calm after accepting my condition” and Factor 4 “Feeling helpless about diabetic nephropathy” showed a weak positive correlation ( $r=0.340$ ).

### **3. Results of reliability and validity examination**

#### **1) Examination results of reliability**

In order to examine the internal consistency reliability between each factor and the overall questionnaire, we acquired Cronbach’s  $\alpha$  coefficient.

Factor 1 was 0.768, Factor 2 was 0.708, Factor 3 was 0.688, and Factor 4 was 0.594. Internal consistency reliability revealed slightly low; however, Cronbach’s  $\alpha$  coefficient was 0.738, which showed there was a certain consistency.

#### **2) Examination results of construct validity**

We examined the construct validity through a comparison of questionnaire items created from categories extracted from the previous study.

Among three categories extracted in the previous study, “Patient anxiety about life and a physical state that requires life-long dialysis” was categorized in Factor 1 and 2, and “There is no cure for diabetes” and “Patients hope that they can maintain their current state” were categorized in Factor 1 and 4. Questionnaire items created from other categories were placed in each factor, respectively.

#### **3) Examination results of discriminant validity**

##### **(Table 4)**

#### **(1) Correlation between each factor score and complications other than diabetic nephropathy**

We examined the difference in each factor score according to the presence or absence of retinopathy and neurosis.

Results revealed significantly high scores for Factor 1 “Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future” and Factor 2 “Becoming calm after accepting my condition” in diabetes patients with retinopathy. Diabetes patients with neurosis revealed significantly high scores for the Factor 1, 2, and 4 “Feeling helpless about diabetic nephropathy.”

#### **(2) Correlation between each factor score and insulin injection**

We examined the difference in each factor score according to the presence or absence of insulin injection.

Diabetes patients using insulin injections revealed significantly high scores in the Factor 1 “Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future,” 2 “Becoming calm after accepting my condition,” and 4 “Feeling helpless about diabetic nephropathy.”

#### **(3) Correlation between each factor score and HbA1c**

We examined the difference in each factor score according to the level of HbA1c. The results showed no significant correlation.

### **V. Discussion**

#### **1. Reliability of questionnaire on perception of patients with diabetic nephropathy**

This study targeted diabetic nephropathy patients

Table 4 Examination results of discriminant validity

	Retinopathy*	Average score	Asymptotic (2-sided)	Neurosis*	Average score	Asymptotic (2-sided)	Insulin injections*	Average score	Asymptotic (2-sided)	HbA1c**	Average score	Asymptotic (2-sided)
<b>Factor 1: Being aware of worsening diabetes and diabetic nephropathy.</b>	Yes	99.38	<b>.027</b>	Yes	105.77	<b>.016</b>	Yes	101.41	<b>.004</b>	Less than 6%	78.50	<b>.286</b>
				No	83.24		No	79.00		6% and greater to less than 7%	92.23	
	No	81.76		No	83.24		No	79.00		7% and greater to less than 8%	79.01	
										8% and greater	96.79	
<b>Factor 2: Being calm after accepting what I have.</b>	Yes	98.12	<b>.049</b>	Yes	112.11	<b>.001</b>	Yes	98.04	<b>.030</b>	Less than 6%	62.00	<b>.198</b>
				No	81.54		No	81.06		6% and greater to less than 7%	90.25	
	No	82.45		No	81.54		No	81.06		7% and greater to less than 8%	83.52	
										8% and greater	98.00	
<b>Factor 3: Slight shock when I was diagnosed with nephropathy.</b>	Yes	87.98	.996	Yes	89.28	.861	Yes	93.09	.249	Less than 6%	79.95	<b>.803</b>
				No	87.66		No	84.08		6% and greater to less than 7%	89.95	
	No	88.01		No	87.66		No	84.08		7% and greater to less than 8%	84.18	
										8% and greater	92.54	
<b>Factor 4: Feeling helpless about diabetic nephropathy.</b>	Yes	93.65	.272	Yes	102.69	<b>.045</b>	Yes	100.89	<b>.006</b>	Less than 6%	104.35	<b>.601</b>
				No	84.06		No	79.31		6% and greater to less than 7%	84.77	
	No	84.90		No	84.06		No	79.31		7% and greater to less than 8%	91.59	
										8% and greater	84.04	

\*Mann-Whitney U Test  
\*\*Kruskal Wallis Test

to create a questionnaire on perception of patients with diabetic nephropathy. In the process of creating the questionnaire, we used the previous study results as a conceptual framework, examined the content and face validity, and arrived at the final items. We selected appropriate items through these processes.

The Cronbach's *a* coefficients were between 0.594 and 0.768, which was relatively low. However, because no value was under 0.5, which generally requires reconsideration, we confirmed internal consistency to some extent.

**2. Validity of questionnaire on perception of patients with diabetic nephropathy**

We examined the comparison of categories in the original draft, the results of factor analysis, and the results of discriminant validity examination.

Among the categories in the original draft, the three categories of "Patient anxiety about life and a physical state that requires life-long dialysis," "There is no cure for diabetes," and "Patients hope they can maintain their current state" were categorized into two factors according to explanatory factor analysis; however, ten other categories were categorized into the same factor. These showed that categories in the previous study and the results of factor analysis matched to a large extent. This suggests construct validity to some extent.

Furthermore, in the uncertainty in illness theory that was used to create the original draft, the type of uncertainty was divided into four categories; namely, "ambiguity of symptoms," "complexity of treatment and healthcare system," "inconsistency in information regarding name and severity of diseases," and

"unpredictability in course of disease and prognosis"<sup>7-8</sup>. We examined the consistency between these four uncertainty domains and each factor extracted by this study.

Factor 1 "Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future" consists of items regarding patient worries and ambiguity about their disease worsening and their uncertain lifestyle in the future. This clearly matched "ambiguity of symptoms."

Factor 2 "Becoming calm after accepting my condition" consists of the concept that patients try to accept nephropathy after experiencing other diseases. This means that patients review their experience and identify that nephropathy develops as a result of complexed causes. Therefore, this factor contains the above-mentioned "complexity of treatment and healthcare system."

Factor 3 "Slight shock when I was diagnosed with nephropathy" contained items regarding patient confusion after being diagnosed with nephropathy because of a lack of knowledge of the disease and symptoms. This matched "inconsistency in information regarding name and severity of diseases."

Factor 4 "Feeling helpless about diabetic nephropathy" means that patients understand that their nephropathy will worsen; however, it is unpredictable and seems impossible for them to do anything. This was very close to "unpredictability in course of disease and prognosis."

The above-mentioned revealed that the questionnaire created in this study matched the uncertainty in illness theory in many points.

In regard to discriminant validity, factors 1, 2, and 4

showed significantly high scores in the group of patients with major diabetic complications other than nephropathy and in the group of patients using insulin.

This questionnaire is designed to measure patient awareness of diabetic nephropathy which has fewer physical symptoms. Significant differences were seen between patients with and without retinopathy and neuropathy, whose sufferers tend to show clear symptoms, and patients using and not using insulin injections on a daily basis, which clarified discriminant validity to some extent.

There was no significant difference between HbA1c and each factor score. This may be due to the fact that these items were due to the asymptomatic nature of the disease.

Any item in Factor 3 did not show significant differences. We need to examine this further in future studies.

### **3. Clinical meaning of the questionnaire created by this study**

We examined the clinical meaning of the questionnaire on perception of patients with diabetic nephropathy.

A previous study clarified that patients with fewer symptoms could realize their physical condition by checking and touching their body, and that doing so could encourage a positive outlook about life with medication<sup>9)</sup>.

Kataoka<sup>10)</sup> reported that as a result of touching their body and feeling something abnormal, patients review their lifestyle and the impact on their physical conditions, which prompts them to think about what to do to improve their condition. This suggested that patients with fewer symptoms can, by touching their body and being aware of abnormality in their physical condition, change their life with medication.

However, patients with diabetic nephropathy tend to notice edema and fatigue, which are major symptoms of nephropathy, when the nephropathy becomes severer. It is thought to be difficult for patients with diabetic nephropathy to notice changes and abnormalities in their physical condition in the early stage.

The questionnaire on perception of patients with diabetic nephropathy created in this study contained items that examined patient perception of their physical condition, future, and lifestyle according to their awareness of their diabetes and diabetic nephropathy, and the experience of having serious disease in their past.

This suggested that the questionnaire on perception

of patients with diabetic nephropathy we created in this study could be applied as a tool to help patients realize their physical condition, especially disease with fewer symptoms, and future prediction.

A previous study regarding education for patients with diabetic nephropathy noted that healthcare providers can't feel awareness of danger for a nephropathy early stage patient<sup>11)</sup>. However, we thought that using the questionnaire created in this study for assessment would make it possible for healthcare providers to understand the complex awareness of their condition and reduce the obstacles to treatment.

### **VI . Limitations of this study**

The questionnaire on perception of patients with diabetic nephropathy was created for patients with diabetic nephropathy who are asymptomatic. Therefore, it is necessary to continue research on patients with active symptoms. Furthermore, the reliability and validity of the questionnaire were confirmed; however, it is necessary to improve accuracy.

### **VII .Conclusion**

We created the questionnaire on perception of patients with diabetic nephropathy. It contains four factors and 20 items with a 50.56% factor contribution ratio. Each factor was named as follows: Factor 1 "Being aware of the worsening of diabetes and the possibility of diabetic nephropathy in the near future;" Factor 2 "Becoming calm after accepting my condition;" Factor 3 "Slight shock when I was diagnosed with nephropathy;" and Factor 4 "Feeling helpless about diabetic nephropathy."

Cronbach's  $\alpha$  coefficients for questionnaire items were between 0.594 and 0.768, which were relatively low. However, the Cronbach's  $\alpha$  coefficient for the overall questionnaire was 0.738. This showed the questionnaire has a certain degree of internal consistency.

In addition, the results of construct and discriminant validities clarified that the questionnaire has a certain validity.

### **VIII .Acknowledgement**

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## 糖尿病性腎症患者の状況の捉え方質問紙の作成

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### 要 旨

【目的】現在、透析導入原因疾患第1位は糖尿病であり、糖尿病患者の透析予防の重要性が高まっている。先行研究にて、自覚症状に乏しい糖尿病性腎症患者は、「状況の捉え方」が療養行動に繋がる可能性が示唆された。そこで本研究では、「糖尿病性腎症患者の状況の捉え方質問紙」を作成し、信頼性と妥当性を検討した。

【研究方法】質問項目作成の理論的枠組みには、先行研究の成果である糖尿病性腎症患者の診断時の認識を説明する10のカテゴリーと24のサブカテゴリーを用いた。調査方法は、質問紙原案28項目（5段階リッカート尺度）、基本属性について自記式質問紙法を用いた。

【調査対象者】研究協力の同意の得られた透析予防指導を実施している病院6施設の糖尿病性腎症2・3期患者175名であった。

【結果】4因子20項目で、因子寄与率50.56%の「糖尿病性腎症患者の状況の捉え方質問紙」を作成した。本質問紙は、信頼性に関してCronbach's  $\alpha$ 係数が.594～.768であり、一定程度確保できていること、構成概念妥当性・弁別的妥当性の検討、およびMishel (1988)の不確かさ理論との比較から妥当性を確保できていることを確認した。質問紙の因子名はそれぞれ、第1因子「将来、糖尿病や糖尿病性腎症が悪化することへの懸念」、第2因子「自分の身体に覚悟をもった冷静さ」、第3因子「腎症と診断された小さな衝撃」、第4因子「糖尿病性腎症は自分の力が及ばない感覚」と命名した。