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Original article

Development and Psychometric validation of the Diabetes Therapy-Related QOL (DTR-QOL) Questionnaire

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Abstract

Objective:
We developed and evaluated the psychometric properties of the Diabetes Therapy-Related QOL (DTR-QOL) as a disease-specific, self-administered questionnaire to assess the influence of diabetes treatment on patient QOL, regardless of treatment method.

Methods:
This new questionnaire was developed and validated in a standardized manner: Item development, pilot-testing and psychometric validation. A survey was conducted using the provisional version of the questionnaire, and reliability and validity were evaluated with psychometric testing.

Results:
The provisional version of the questionnaire was generated with 29 items through literature review and pilot testing. For psychometric assessment, analyses were performed on the responses of 284 adult Japanese patients with diabetes. Factor analysis by the principal factor method with promax rotation revealed 4 factors; ''burden on social activities and daily activities'' (13 items), ''anxiety and dissatisfaction with treatment'' (8 items), ''hypoglycemia'' (4 items), and ''satisfaction with treatment'' (4 items). For reliability, the intraclass correlation was 0.92, and Cronbach's alpha coefficient was 0.94, indicating adequate test-retest reliability and internal consistency. For known-group validity, there were significant differences in scores for following variables: age, diabetes type, HbA1c, treatment method, glycemic control, hypoglycemia, nocturnal hypoglycemia, concern about weight gain, health status (patient assessment), and degree of communication with physician.

Conclusions:
The DTR-QOL, with good reliability and validity, can assess the influence of diabetes treatment on patient QOL. The DTR-QOL can be used regardless of treatment method that patients receive, and this characteristic enables to detect a difference on patients QOL between treatment methods before and after a switch of treatment. Limitations of this study include representativeness of the patient sample. The relatively small number of patients with type 1 diabetes should be noted. Also, responsiveness of the DTR-QOL has not yet been examined.

Introduction

The goal of diabetes treatment is to maintain a quality of life (QOL) and longevity that are no different from those of an otherwise healthy person. To achieve this goal, efforts must be made to maintain good glycemic control, weight, blood pressure, and serum lipid levels to prevent the onset and progression of diabetic microangiopathy, including retinopathy, nephropathy, and neuropathy, as well as arteriosclerotic disease, including ischemic heart disease,

cerebrovascular disease, and arteriosclerosis obliterans. For effective treatment, a therapeutic strategy must be designed which takes into account various factors, including age, disease status, and glycemic control, and complications.

When treatment satisfaction is low, or when QOL diminishes as a result of treatment, motivation and adherence with treatment decrease[1,2]. Even if an effective treatment regimen is provided, it may not be followed by patients, and an effective therapeutic effect may not be achieved. On the other hand, when patients are satisfied with their treatment, adherence with treatment increases[3], and both good physical and mental health can be maintained[4]. Therefore, to assess a patient's condition comprehensively and to decide whether or not treatment is successful, in addition to glycemic control markers, a multifaceted evaluation of patient QOL is important. These include degree of satisfaction with treatment, degree of impairment of daily and social activities, and mental health status.

Patient QOL is usually assessed subjectively by patients themselves using a questionnaire. Questionnaires are classified into comprehensive and specific scales, depending on the targeted respondents and the nature and degree of the concept being measured[5]. For highly sensitive assessment of the condition of patients with a particular disease, questionnaires should be disease-specific[6]. Many questionnaires to assess QOL in patients with diabetes have been developed, but most have been designed assuming a specific type of disease, treatment method, or a specific regimen and route of administration among treatment methods[7]. In fact, few questionnaires can be used for all types of diabetes treatment in Japan, except for the Diabetes Treatment Satisfaction Questionnaire (DTSQ). Although this simple 8-item questionnaire has the advantageous characteristic of convenience in usage because of its small number of questions, one weakness is that a wide range of specific impacts cannot be captured due to the limited number of questions. Therefore, as a self-administered questionnaire to assess the influence of diabetes treatment on patient QOL, regardless of treatment method, we developed the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire and assessed its psychometric properties.

Patients and methods

1. Development of questionnaire

We set the following requirements which this newly developed DTR-QOL should satisfy: 1) it should be able to measure the influence of treatment on patient QOL, 2) it should be able to assess the patient's comfort and satisfaction with treatment, and 3) it can be used regardless of the type of treatment that a patient is receiving. The influence of treatment on patient QOL is classified into the domains of daily activities, social activities, and somatic symptoms. Based on these fundamental concepts, proposed questionnaire items were generated with reference to the relevant literature and to questionnaires in whose development the authors have previously been involved: Insulin Therapy Related QOL [ITR-QOL][8], the Japanese version of the Diabetes Treatment Satisfaction Questionnaire [DTSQ][9,10], and the Japanese version of the Diabetes Medication Satisfaction Questionnaire [DiabMedSat][11,12]. Taking into consideration ease of use in daily clinical practice, we avoided including too many questionnaire items.

In generating the proposed questionnaire items, patient interviews were conducted. The main purpose of this interview was exploration for patient-perceived impacts of diabetic treatment on the social, psychological, and physical aspects of their life. Based on information obtained by the interviews and results of cognitive debriefing, the proposed questionnaire items were selected and repeatedly revised to improve question content and the preciseness of wording. Finally, a provisional version of the questionnaire was generated with 29 items.

The response scale used was a 7-point Likert scale (1: Strongly agree – 7: Strongly disagree). The score of each item was reversed so that 7 represented the highest QOL. The total score, after simple addition of the item scores, was converted to 0–100 (best-case response = 100; worst-case response = 0). The domain score was calculated from the mean score of the attribute items, and the scoring range was converted to 0–100. If there were missing values for any item belonging to a domain, they were handled in the following manner. If the number of items with a missing value in the domain was less than 50% of the total items in that domain, the mean value excluding the missing value(s) was calculated and substituted for the missing value(s). If the number of items with a missing value in the domain was 50% or more of the total items in that domain, the domain score was not calculated. In addition, if even one domain score could not be calculated, the total score was not calculated.

2. Patient survey and psychometric testing

A patient survey was conducted using the provisional version of the questionnaire, and its reliability and validity were evaluated with psychometric testing. The survey participants were male and female patients with either type 1 or 2 diabetes, at least 18 years old, who were outpatients at Tenri Hospital in Japan. For enrollment of participants, the purpose of the survey was explained at outpatient visits, and written informed consent was obtained. Participants who provided consent were given the survey

and asked to respond promptly. In addition to the provisional version of the DTR-QOL, the survey questionnaire included the Japanese version of the DTSQ[10] and the Japanese version of the SF-8 (SF-8 Health Survey)[13] as external standards for validity evaluation. Several questions about glycemic control, hypoglycemia, and treatment compliance were also included. The DTSQ is a widely used questionnaire consisting of 8 items that can conveniently assess diabetes treatment satisfaction. The SF-8 is a comprehensive health-related QOL index consisting of 8 items to comprehensively evaluate health-related QOL. The SF-8 is structured to be scored by the same measurement standards as the SF-36, which is a major health-related QOL scale. In consideration of the age of potential participants, and possible diabetic complications such as retinopathy and neuropathy, we decided to use the SF-8 rather than SF-36 to reduce the burden on participants.

To evaluate reproducibility, patients whose symptoms and treatment course were judged to be stable were asked to respond to the provisional version of the DTR-QOL again after an interval of at least 1 day (test-retest). HbA1c levels measured at outpatient visits when consent was obtained were used as a variable for known-group validity evaluation.

3. Statistical analysis

For item analysis, the basic statistics of the item scores were calculated, and the following applicable items were intended for deletion: 1) items for which 80% or more of the respondents showed a floor effect or ceiling effect; 2) either one of the items for which the correlation coefficient between items was $\geq$0.8; and 3) if the correlation coefficient between each item and the total score, excluding an item, was very low compared to that of other items.

For reliability, internal consistency and reproducibility were evaluated. For internal consistency, homogeneity of questionnaire items within each domain was examined by Cronbach's α coefficient. Reproducibility between the two sets of response results by patients with stable symptoms and treatment was examined using the intraclass correlation coefficient (ICC).

For validity, construct validity (domain structure), concurrent validity, and known-group validity were examined. For construct validity, the structure of the questionnaire was explored using factor analysis (principal factor method with promax rotation). For concurrent validity, correlation with the DTSQ and SF-8, as external standards, was examined using the Pearson product-moment correlation coefficient. The correlation coefficient was interpreted as: 0.1, weak correlation; 0.3, moderate correlation; and 0.5, strong correlation, according to criteria proposed by Cohen for representing correlation strength in psychometric testing[14]. For known-group validity, major background variables that might affect scores were selected, and the relationship between categorized variables and domain scores was examined by using t-test or analysis of variance, depending on the number of categories in a selected variable. Statistical tests were two-sided with a level of significance of 5%.

Results

1. Validation sample

From May to September 2010, the survey was distributed to 299 patients and returned by 284 patients (return rate, 95.0%). For evaluation of reproducibility, the questionnaire was distributed to 100 patients and returned by 91 patients. The questionnaires of the 84 patients without missing background information or deficiencies in their questionnaires were analyzed for reproducibility. Table 1 shows the attributes of the 284 patients who returned the questionnaire. The mean age (±standard deviation) was 64.0 ± 11.6 years; there were 170 males (59.9%) and 114 females (40.1%). Diabetes type was type 1 in 22 patients (7.8%) and type 2 in 260 patients (92.2%). The mean HbA1c (NGSP value) was 7.2% ± 0.9%. Treatment was "diet alone" in 35 patients (12.3%), "oral antidiabetic drugs (OADs) alone" in 117 patients (41.2%), "insulin alone" in 107 patients (37.7%), and "insulin + OAD(s)" in 25 patients (8.8%).

Table 1. Backgrounds of the analysis set (n = 284).

Characteristics		
Age (n, Mean ± SD)	280	64.0 ± 11.6
Sex (n, %)		
Male	170	59.9
Female	114	40.1
Diabetes type (n, %)		
Type 1	22	7.8
Type 2	260	92.2
Treatment (n, %)		
Diet alone	35	12.3
Oral antidiabetic drug(s) alone	117	41.2
Insulin alone	107	37.7
Insulin + Oral antidiabetic drug(s)	25	8.8
Concomitant disease (n, %)		
Nephropathy		
Yes	84	30.0
No	196	70.0
Retinopathy		
Yes	84	30.8
No	189	69.2
Neuropathy		
Yes	116	41.1
No	166	58.9
HbA1c (% [NGSP value]) (n, Mean ± SD)	283	7.2 ± 0.9

2. Item analysis

The results of item analysis in the 284 patients showed no floor or ceiling effect in the response distributions. The percentage of patients who showed extreme responses (1 or 7) ranged between 23.2% and 66.2% for answer "1", and between 0.4% and 11.6% for answer "7". Item pairs were examined for a correlation coefficient of ≥0.8 between items. Among 3 items (Q16: I am scared because of low blood sugar, Q17: I am sometimes bothered by low blood sugar, and Q18: Symptoms due to low blood sugar are uncomfortable), the correlation coefficients were Q16 and Q17 = 0.87, Q16 and Q18 = 0.86, and Q17 and Q18 = 0.91. Because each of these questionnaire items was important for measuring the influence of hypoglycemia on patients, they were not deleted in light of the purpose of the questionnaire. There were no applicable items in which the correlation coefficient between each questionnaire item and the total score, excluding that item, was very low compared to the other items.

3. DTR-QOL structure

The DTR-QOL domain structure was examined using factor analysis by the principal factor method with promax rotation. The factor analysis extracted 4 factors based on interpretability. The factor contribution rate of these 4 factors was 0.62, 0.14, 0.11, and 0.05, respectively, and the cumulative contribution rate was 0.92 (Table 2). From the content of the attribute questionnaire items, factor 1 was termed as "burden on social activities and daily activities" (13 items), factor 2 as "anxiety and dissatisfaction with treatment" (8 items), factor 3 as "hypoglycemia" (4 items), and factor 4 as "satisfaction with treatment" (4 items) (Table 3). For Q8 (I feel like my current diabetes treatment takes away the enjoyment of eating) and Q9 (With my current diabetes treatment, it is hard to curb my appetite), the factor loading (Q8: 0.43 and 0.40; Q9: 0.39 and 0.44) was similar in factors 1 and 2. Based on their content, these items were included in factor 1.

4. Reliability

Cronbach's α coefficient, an internal consistency index, was good (≥0.81) for all factors (Table 4). The questionnaire items belonging to each factor were confirmed to have the same concept. For the entire survey, the α coefficient was 0.94. In addition, the intraclass correlation coefficient was 0.92; suggesting acceptable reproducibility.

Table 2. Construct validity (the evaluation of domain structure): factor loading.

Item no.	Factor 1	Factor 2	Factor 3	Factor 4
1	0.62	0.11	−0.03	−0.02
2	0.67	0.05	0.03	0.06
3	0.71	−0.06	−0.03	0.11
4	0.72	−0.10	0.14	0.05
5	0.71	0.12	−0.03	−0.19
6	0.75	−0.02	0.03	−0.01
7	0.64	0.14	−0.03	−0.03
8	0.43	0.40	−0.15	0.04
9	0.39	0.44	−0.17	0.07
10	0.65	0.05	0.14	0.05
11	0.72	0.08	−0.03	0.06
12	0.49	−0.09	0.20	0.01
13	0.42	−0.02	0.14	−0.07
14	0.19	0.46	0.09	−0.11
15	0.12	0.07	0.66	0.07
16	0.02	0.05	0.90	0.01
17	0.02	0.01	0.93	−0.03
18	0.02	0.04	0.89	0.00
19	0.03	0.66	0.22	−0.15
20	−0.13	0.90	−0.07	−0.02
21	−0.03	0.65	0.18	0.10
22	0.03	0.62	0.10	0.14
23	0.14	0.61	0.09	0.10
24	0.06	0.63	0.04	0.10
25	0.16	0.52	−0.03	0.13
26	−0.12	0.26	−0.09	0.61
27	−0.10	0.20	0.01	0.69
28	0.06	−0.09	0.05	0.73
29	0.10	−0.07	0.04	0.72
Factor contribution rate	0.62	0.14	0.11	0.05

Notes: Principal factor method (promax rotation) was used.
indicates factor pattern ≥0.4
indicates attributed domain

5. Concurrent validity

Correlation coefficients of DTR-QOL with the DTSQ and SF-8 summary scores (PCS and MCS) were calculated (Table 5). The correlation coefficient with the DTSQ was 0.35, and the correlation coefficients with the SF-8 summary scores were 0.34 and 0.44. Moderate or greater positive correlations were indicated (all $P < 0.05$).

6. Known-group validity

Variables that might affect DTR-QOL scores were selected, and their relationships to the total score were

Table 3. DTR-QOL domain structure.

Factor 1: Burden on social activities and daily activities	
1	My current diabetes treatment interferes with my work and activities.
2	My current diabetes treatment limits the scope of my activities.
3	It is difficult to find places on time for my current diabetes treatment.
4	My current diabetes treatment interferes with group activities and personal friendships.
5	It is a burden getting up at a certain time every morning for my current diabetes treatment.
6	With my current diabetes treatment, the restricted meal times are a burden.
7	When I eat out, it is difficult to manage my current diabetes treatment.
8	I feel like my current diabetes treatment takes away the enjoyment of eating.
9	With my current diabetes treatment, it is hard to curb my appetite.
10	The time and effort to manage my current diabetes treatment are a burden.
11	I am constantly concerned about time to manage my current diabetes treatment.
12	Pain due to my current diabetes treatment is uncomfortable.
13	Gastrointestinal symptoms (nausea, passing gas, diarrhea, abdominal pain) due to my current diabetes treatment are uncomfortable.
Factor 2: Anxiety and dissatisfaction with treatment	
14	I am bothered by weight gain with my current diabetes treatment.
19	I have uncomfortable symptoms due to hyperglycemia (high blood glucose).
20	I am worried about high blood glucose.
21	I am dissatisfied that my blood glucose is unstable (high and low).
22	I am worried that complications might get worse with my current diabetes treatment.
23	I get anxious thinking about living while on my current diabetes treatment.
24	I find it unbearable to think that even if I continue my current diabetes treatment, my diabetes may not be cured.
25	I am concerned that if I continue my current diabetes treatment, the efficacy (effectiveness) may diminish.
Factor 3: Hypoglycemia	
15	I worry about low blood glucose due to my current diabetes treatment.
16	I am scared because of low blood glucose.
17	I am sometimes bothered by low blood glucose.
18	Symptoms due to low blood glucose are uncomfortable.
Factor 4: Satisfaction with treatment	
26	Overall, I am satisfied with my current blood sugar control (glycemic control).
27	With my current diabetes treatment, I am confident that I can maintain good blood glucose control.
28	I am hopeful about the future with my current diabetes treatment.
29	With regards to diabetes treatment, I am satisfied with current treatment methods.

examined (Table 6). There were significant differences in scores for the following variables: age, diabetes type, HbA1c, treatment method, glycemic control (patient assessment), hypoglycemia, nocturnal hypoglycemia, concern about weight gain, current health status (patient assessment), and degree of communication with physician. No significant difference was observed by sex.

Among these items, significant differences in DTSQ score trends were observed for only 3 items: glycemic control (very good: 32.6 [$n = 30$], good: 30.6 [$n = 144$], neither good nor poor: 28.2 [$n = 80$], poor: 31.3 [$n = 24$], very poor: 26.8 [$n = 4$]; $P = 0.0045$); health status (good: 32.2 [$n = 85$], somewhat good: 30.3 [$n = 107$], neither good nor poor: 28.4 [$n = 57$], somewhat poor: 27.5 [$n = 32$], poor: 29.0 [$n = 1$]; $P = 0.0005$); and degree of communication with physician (good communication: 31.7 [$n = 155$], some communication: 28.5 [$n = 108$], cannot say one way or the other: 27.8 [$n = 13$], not much communication: 25.0 [$n = 5$], no communication: 15.0 [$n = 1$]; $P < 0.0001$).

In relation to treatment method, there was a significant difference among treatment methods ($P < 0.0001$). Better scores were indicated in the following order from highest to lowest: diet alone, oral antidiabetic drug alone, oral antidiabetic drug(s) + insulin, and insulin alone. For glycemic control in the previous 1 month (response choices: very good, good, neither good nor poor, poor, and very poor), there was also a significant difference among response choices ($P < 0.0001$). Patients who were cognizant of good glycemic control were more likely to show higher mean DTR-QOL scores. HbA1c was classified into 3 categories: ≤6.9%, 7.0-8.3%, and ≥8.4%. There was a significant difference ($P < 0.0001$) among the 3 groups, with highest scores in the ≤6.9% group. Patients who responded "no" to having experienced hypoglycemia in the previous 1 month had higher scores ($p < 0.0001$). Regarding concern about weight gain (response choices: not concerned at all, not very concerned, maybe a bit concerned, somewhat concerned, and very concerned), there was a significant difference among response choices ($P < 0.0001$). The less the concern, the higher the scores tended to be.

Table 4. Domain scores and Cronbach α coefficient.

	No. of items	Mean ± SD	Median [Minimum-Maximum]	Cronbach α coefficient
Factor 1: Burden on social activities and daily activities	13	81.4 ± 17.7	85.9 [6.4–100.0]	0.91
Factor 2: Anxiety and dissatisfaction with treatment	8	69.3 ± 23.7	68.8 [6.3–100.0]	0.89
Factor 3: Hypoglycemia	4	79.1 ± 27.2	91.7 [0.0–100.0]	0.93
Factor 4: Satisfaction with treatment	4	66.5 ± 21.5	62.5 [0.00–66.5]	0.81
Total	29	75.7 ± 17.3	77.6 [21.8–100.0]	0.94

Score range: 0–100. The higher score indicates higher QOL.

Table 5. Concurrent validity: Correlation coefficients between DTR-QOL and the external standards ($n = 284$).

	DTR-QOL	DTSQ	SF-8 (PCS)*	SF-8 (MCS)†
DTR-QOL	–	0.35	0.34	0.44
DTSQ	0.35	–	0.18	0.19
SF-8 (PCS)*	0.34	0.18	–	0.07
SF-8 (MCS)†	0.44	0.19	0.07	–

Coefficients are Pearson's product-moment correlation coefficient, all P values <0.05
*PCS is physical component summary
†MCS is mental component summary

Discussion

For diabetes treatment in Japan, in addition to many types of OADs and insulin preparations, GLP-1 receptor agonists are currently available. Increased treatment options have contributed to the achievement of better glycemic control compared to before. However, treatment of diabetes requires long-term management, and if QOL is diminished due to treatment, or if patients are not sufficiently satisfied with treatment, optimal treatment efficacy cannot be achieved. Therefore, patient QOL and treatment satisfaction as a treatment outcome should be taken into account in addition to glycemic control

Table 6. Discriminant validity: relationship between the factors that may affect the DTR-QOL scores and the actual total scores.

Factors	n	Mean ± SD	P value*
Sex			
Male	169	76.6 ± 17.1	0.3077
Female	114	74.4 ± 17.6	
Age in years			
<65	126	72.3 ± 16.5	0.0035
≥65	153	78.4 ± 17.5	
Diabetes type			
Type 1	22	60.9 ± 17.0	0.0001
Type 2	259	77.0 ± 16.8	
HbA1c			
6.9≥	105	80.6 ± 16.6	<0.0001
7.0–8.3	149	74.1 ± 17.0	
8.4≤	28	65.7 ± 16.2	
Treatment			
Diet alone	34	82.3 ± 14.6	<0.0001
Oral antidiabetic drug(s) alone	117	80.7 ± 15.3	
Insulin + Oral antidiabetic drug(s)	25	72.6 ± 15.9	
Insulin alone	107	68.9 ± 18.1	
Glycemic control in the past 1 month (patient assessment)			
Very good	30	83.4 ± 16.5	<0.0001
Good	144	79.6 ± 16.9	
Neither good nor poor	80	70.1 ± 15.7	
Poor	24	65.7 ± 14.5	
Very poor	4	54.9 ± 10.6	
Hypoglycemia in the past 1 month			
Yes	64	65.8 ± 18.3	<0.0001
No	216	78.7 ± 15.9	
Nocturnal hypoglycemia in the past 1 month			
Yes	17	61.5 ± 19.0	0.0004
No	265	76.7 ± 16.8	
Concern about weight gain in the past year			
Not concerned at all	116	81.4 ± 15.7	<0.0001
Not very concerned	75	75.0 ± 16.9	
Maybe a bit concerned	32	72.3 ± 14.5	
Somewhat concerned	49	68.0 ± 17.7	
Very concerned	9	62.7 ± 22.7	
Health status (patient assessment)			
Good	85	84.9 ± 14.5	<0.0001
Somewhat good	107	76.2 ± 17.0	
Neither good nor poor	57	66.6 ± 15.1	
Somewhat poor	32	67.8 ± 14.6	
Poor	1	27.6	
Degree of communication on treatment with physician			
Good communication	155	78.7 ± 16.8	0.0098
Some communication	108	73.2 ± 17.5	
Cannot say one way or the other	13	68.9 ± 14.9	
Not much communication	5	63.7 ± 18.9	
No communication	1	52.9	

*For 2 categories, the unpaired t-test was used, and for ≥3 categories, analysis of variance was used.

and safety. Although QOL assessment using questionnaires has become a part of treatment evaluation, most of the questionnaires currently used are targeted at a specific treatment method or diabetes type, and few questionnaires can be used for a broad range of patients.

We developed the DTR-QOL as a questionnaire that can be used for patients with diabetes on various types of treatment. The reliability and validity of the questionnaire were evaluated psychometrically, using survey results obtained from 284 Japanese patients with diabetes. Regarding a domain structure, a four-factor model ("burden on social activities and daily activities," "anxiety and dissatisfaction with treatment," "hypoglycemia," and "satisfaction with treatment") was employed from the result of exploratory factor analysis. Two items (Q8 & 9) did not clearly separate to a specific factor, and these were assigned to the factor 1 that seemed most appropriate based on conceptual interpretability. Despite the unclear loading of these items, the DTR-QOL still showed sufficient internal consistency with Cronbach's α statistic of 0.91 for the factor 1, and therefore, acceptable construct validity was considered to be restored.

For reliability, as touched upon earlier, sufficient internal consistency was demonstrated with Cronbach's α coefficient of 0.81-0.93, and the acceptable reproducibility was demonstrated with an intraclass correlation coefficient of 0.92. For validity, concurrent validity was considered to be verified since the DTR-QOL score moderately correlated with the DTSQ and SF-8. This showed that the higher the treatment satisfaction and general health status were, the higher the patient QOL was, as assessed by the DTR-QOL.

For known-group validity, the relationships between variables that might affect scores and the DTR-QOL score were examined. As a result, patients with better glycemic control, patients with fewer episodes of hypoglycemia, patients less bothered by weight gain, patients with better health status, and patients who had better communication with their physicians had significantly higher DTR-QOL scores. This demonstrates that the DTR-QOL has good discriminant ability for these factors, which means that variables such as glycemic control, hypoglycemia, weight gain, overall health status, and communication with their physician are factors that influence the QOL of patients receiving diabetes treatment. Furthermore, among treatment methods, scores were highest for diet alone, followed in descending order by OADs alone, OAD(s) + insulin, and insulin alone. Insulin treatment is a major potential factor adversely impacting treatment satisfaction, as well as factors such as diabetic complications and inadequate HbA1c levels[15]. In the present study, as expected, lower scores were observed in patients receiving insulin compared to other treatment methods. However, it should be noted that patient characteristics can be biased because patients were not randomly allocated to the treatment groups in this study. Also, insulin initiation did not adversely impact patient QOL[16], suggesting that patient QOL may not be impaired if improvement of glycemic level is achieved.

The DTR-QOL is a questionnaire that can be used regardless of diabetes type or treatment method. When measuring patient QOL longitudinally as a part of treatment evaluation, assessment using the same questionnaire, in other words, the same assessment index, is preferable. In diabetes treatment, however, changes in treatment method are common, and a different questionnaire may have to be used every time treatment is switched. This prevents longitudinal QOL assessment over a long time period. If assessment using the same index can be assured even if treatment is changed, management strategy to recover QOL domains impaired by current treatment can be developed effectively from a long-term perspective. These management strategies include switching regimens and treatment methods, and patient education. As a result, improved QOL may contribute to improved treatment outcomes.

Several limitations in this study should be noted. First, psychometric evaluation of this questionnaire was performed using responses from Japanese patients with diabetes, and the possibility that the results were influenced by ethnicity cannot be excluded. Next is the representativeness of our patient sample for analysis. In this study, no specific enrollment criteria were established, and patients receiving diabetes treatment were broadly and consecutively enrolled. However, since this study was conducted at a single medical institution, our sample may be biased. We also note that there were a relatively small number of patients with type 1 diabetes in this study. However, we still believe the DTR-QOL can be used for patients with type 1 diabetes because a significantly higher treatment impact was detected in patients with type 1 diabetes compared with type 2 diabetic patients. In addition, responsiveness of the DTR-QOL has not yet been examined. Questionnaires with assured reliability and validity are assumed to have sufficient responsiveness to detect clinically meaningful changes[17]. Because the DTR-QOL was shown to have sufficient discriminant ability to detect differences in background factors, we believe that responsiveness was assured to some extent. Future studies would be helpful to assess responsiveness in actual cases. Moreover, this questionnaire was developed in Japanese, so that when used in languages other than Japanese, a translated version must be linguistically validated, and its psychometric properties must be confirmed[18,19].

Conclusion

The DTR-QOL, with good reliability and validity, can assess the influence of diabetes treatment on patient QOL, regardless of treatment method. The DTR-QOL

assesses patient QOL from the perspective of four factors: "burden on social activities and daily activities," "anxiety and dissatisfaction with treatment," "hypoglycemia," and "satisfaction with treatment." The DTR-QOL can be useful in evaluating new drugs and treatment methods. The questionnaire can be practically used in daily clinical practice.

Transparency

Declaration of funding
Novo Nordisk A/S provided financial support for this study.

Declaration of financial/other relationships
HI has disclosed that he received sponsorship from Novo Nordisk to conduct this study.

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