Development and evaluation of the Japanese version of the Audit of Diabetes-Dependent Quality of Life for patients with diabetes

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Abstract

Objectives Our objective was to undertake linguistic validation and cultural adaptation of the Japanese version of the Audit of Diabetes-Dependent Quality of Life (JP-ADDQoL) and to evaluate its psychometric properties when completed by Japanese patients with diabetes.

Methods We followed the standard linguistic validation procedure and subsequently evaluated the reliability (internal consistency) and construct validity (exploratory and confirmatory factor analyses) of the translated version by surveying 239 Japanese patients with diabetes.

Results We translated 19 items for the JP-ADDQoL. The internal consistency was excellent (Cronbach's $\alpha = 0.933$). In the exploratory factor analysis, four factors were extracted, and most of the items in all four factors had high loadings. Forced one-factor analysis revealed all factor loadings other than those for sex life to be >0.40 (sex life: 0.398). Confirmatory factor analysis indicated an acceptable fit for the JP-ADDQoL.

Conclusions The JP-ADDQoL showed adequate reliability and acceptable validity. Examining not only the impact of diabetes on a specific domain of life but also its importance for each patient leads to more accurate and individualized measurement of the patient's QoL.

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Introduction

Diabetes is a disease that can profoundly affect the patient's quality of life (QoL) [1]. Anderson et al. [2] reported results of a meta-analysis indicating that the presence of diabetes doubles the odds of comorbid depression and noted that approximately 30 % of patients with diabetes reported elevated depressive symptoms in self-report measures. In addition, poor patient-reported outcomes (PROs) are often related to reduced regimen adherence [3], which leads to poor glycemic control or development of late complications [4]. Therefore, regular assessment of PROs is important in diabetes.

The Audit of Diabetes-Dependent Quality of Life (ADDQoL) is a specifically diabetes-related QoL measurement scale: it examines the patient's perception of the impact of diabetes on specific domains of life and of the

importance of those domains for QoL [5–14]. The original English version of the ADDQoL [5, 6] was developed in 1994 and has since been revised. The latest version is the ADDQoL 19, which includes 19 domain-specific items and two overview items [7–9]. In their respective review studies, Garratt et al. [15] and Speight et al. [16] concluded that good evidence exists for the reliability and construct validity of the ADDQoL.

Other than the ADDQoL, many scales have been developed to assess diabetes-related outcomes and subsequently translated into Japanese; they include the Diabetes Quality of Life (DQoL) [17], Problem Areas in Diabetes (PAID) [18], Elderly Diabetes Burden Scale (EDBS) [19], and Diabetes-Therapy-Related QoL (DTR-QoL) [20] scales. The DQoL scale is a widely used scale that measures satisfaction with treatment, impact of treatment, worry about the future effects of diabetes, worry about social and vocational issues, and overall well-being [5]. Also, PAID is one of the most widely known scales and measures the burden of illness by surveying patients' feelings about the condition and its treatment, satisfaction with treatment, and worries about the future [18]. EDBS evaluates the burden in elderly diabetic individuals through measuring social burden, dietary restrictions, worry about diabetes, burden by tablets or insulin, treatment dissatisfaction, and symptom burden [19]. The EDBS was developed in Japan and translated into Turkish. The DTR-QoL scale is a relatively newly developed Japanese questionnaire that focuses on burden on social activities and daily activities, anxiety and dissatisfaction with treatment, hypoglycemia, and satisfaction with treatment [20]. All of these questionnaires are well validated and useful to measure diabetes-related outcome in patients with diabetes. Differences between these scales and the ADDQoL are that the ADDQoL focuses on the influence of diabetes on particular aspects of life, not on the burden of the disease or satisfaction with diabetes treatment. For example, these questionnaires do not measure the effect diabetes has on the patient's sex life. Sex-related questions are important for patients with diabetes because diabetes can affect sexual function [21]. In addition, the questionnaires do not take into account the difference in patients' living conditions. For example, diabetes influences QoL differently depending on the patient's employment status. Moreover, the ADDQoL has been available in more than 80 countries and for various racial groups, including Asian populations [8–12], but had not been translated into Japanese.

Therefore, the objective of this study was to develop a linguistically and psychometrically validated Japanese version of the ADDQoL for Japanese patients with diabetes.

Materials and methods

Instrument

The ADDQoL contains two overview questions to measure (1) the patient's overall QoL and (2) how the patient's QoL would change if he or she did not have diabetes. An additional 19 specific items measure (a) impact on QoL (how each aspect of life would change if the patient did not have diabetes) and (b) importance of a specific item (how important each of these 19 aspects of life is to the patient's QoL). A 5-point Likert scale is used (−3: very much better to 1: worse) to measure the impact on QoL and a 4-point Likert scale (3: very important to 0: not at all important) is used to measure importance. Weighted impact scores for each domain are calculated by multiplying the two scales [range −9 to +3; more negative scores indicate a greater negative impact of diabetes on QoL, while positive scores (only rarely seen) indicate a positive impact of diabetes on QoL]. The average weighted impact score (AWI) is calculated by summing the weighted impact scores for all applicable domains and dividing these by the number of applicable domains for each respondent.

The translation procedure was based on the guidelines of the MAPI Research Institute [22]. Translation of the ADDQoL proceeded as follows: (1) Authorization by the author was obtained. (2) A translation group was set up consisting of endocrinologists, medical writers, and a psychologist. (3) Two members (an endocrinologist and a psychologist), who are native Japanese speakers and fluent in English, independently translated the questionnaire into Japanese (forward-translation step). (4) The two forward translations were compared and then reconciled into a single version. (5) Two native English speakers (medical writers) who are fluent in Japanese each produced a backward translation of the forward translation draft (backward-translation step). (6) The backward-translation manuscripts were compared with the original version, and the forward-translation manuscript was modified in consultation with the author's team of linguists when differences between the backward translation and the original version were found (harmonization review). (7) Steps (3) to (6) were repeated until a linguistically comparable and satisfactory version had been developed. (8) The latest version was reviewed and evaluated by a psychologist and a clinical endocrinologist to determine whether the Japanese wording was appropriate and likely to be understood by clinical patients (revision step). (9) Five volunteers with diabetes were interviewed with the aim of confirming the simplicity and comprehensibility of the questionnaire for clinical application (cognitive debriefing step).

Thus, we obtained the final version of the Japanese ADDQoL (JP-ADDQoL).

Study participants

A patient survey using the JP-ADDQoL was conducted, and its reliability and validity were evaluated by psychometric testing. The survey participants were 239 Japanese patients with diabetes aged ≥ 18 years who were selected by convenience sampling from the outpatient clinic of the University of Tsukuba Mito Medical Center during May and June 2013. In addition to the JP-ADDQoL, data on the patients' demographic characteristics (such as duration of diabetes, existing diabetic complications, and medications) and PAID scores were collected by questionnaire. Written informed consent was obtained from all participants. The study protocol was consistent with the Japanese government's *Ethical Guidelines Regarding Epidemiological Studies* and in accordance with the Declaration of Helsinki and was reviewed by the institutional review board of the University of Tsukuba Mito Medical Center.

Statistical analysis

To evaluate the reliability of the JP-ADDQoL, its internal consistency was evaluated using Cronbach's alpha coefficient. To evaluate its validity, the structure of the questionnaire was explored by factor analysis (maximum-likelihood method with promax rotation). Subsequently, confirmatory factor analysis (CFA) was conducted to examine construct validity. For the CFA, we used the following fit indices: the χ^2 (and the respective degrees of freedom, df), goodness of fit index (GFI), comparative fit index (CFI), and root-mean-square error of approximation (RMSEA). Previous reports suggested that GFI and CFI values >0.90 [23, 24] and RMSEA <0.08 [25] are good-fitting models. In addition, we compared the AWI with participants' disease-related characteristics by using the *t* test or the Mann–Whitney test. Pearson's correlation coefficients were estimated to assess the relationships between the JP-ADDQoL score and continuous variables. Statistical tests were two-sided, with a significance level of 5 %. IBM SPSS Statistics 21 for Windows was used to examine all analyses other than the CFA, for which IBS SPSS Amos 22.0 was used.

Results

Participants' characteristics

Eighty of 239 participants were excluded owing to deficient items (51 skipped a question; 29 skipped either impact or importance). Consequently, 159 participants [92

men (57.9 %) and 67 women (42.1 %)] were eligible for the current analysis. Their mean age was 59.7 ± 12.6 years, and their mean body mass index (BMI) was 24.5 ± 4.5 kg/m². Twenty-four participants (15.0 %) had type 1 diabetes and 135 (84.9 %) had type 2 diabetes. Sixty-five participants (40.9 %) reported some diabetic complications, and 80 participants (50.3 %) were receiving insulin treatment. No correlations were found between JP-ADDQoL scores and age ($r = 0.13$, $P = 0.10$), duration of diabetes ($r = -0.09$, $P = 0.25$), and BMI ($r = -0.04$, $P = 0.60$). Table 1 shows the AWI by disease-related characteristics of participants. Participants who were female, younger, had type 1 diabetes, and a longer duration of diabetes had worse JP-ADDQoL scores compared with those who were male, older, had type 2 diabetes, and a shorter duration of diabetes, respectively; however, the difference was not significant. On the other hand, participants who had a glycosylated hemoglobin (HbA_{1c}) value ≥ 7.0 (53 mmol/mol), had diabetic complications, or were

Table 1 Average weighted impact scores (AWI) by participants' disease-related characteristics

	No.	Mean $\pm$ SD	<i>P</i> value
Sex			
Male	92	-1.79 ± 1.39	0.46
Female	67	-1.97 ± 1.63	
Age (years)			
≤ 60	77	-2.03 ± 1.57	0.19
> 60	82	-1.71 ± 1.32	
Diabetes duration (years)			
< 10	82	-1.77 ± 1.54	0.40
≥ 10	77	-1.97 ± 1.45	
Diabetes type			
Type 1	24	-2.36 ± 1.83	0.08
Type 2	135	-1.78 ± 1.42	
HbA _{1c} (%)			
< 7.0 (53 mmol/mol)	46	-1.56 ± 1.55	0.02
≥ 7.0	104	-2.01 ± 1.45	
Unknown	9	-1.73 ± 1.73	
Diabetes complication			
Yes	65	-2.32 ± 1.38	< 0.01
No	83	-1.57 ± 1.51	
Unknown	11	-1.43 ± 1.54	
Insulin treatment			
Yes	80	-2.29 ± 1.56	< 0.01
No	79	-1.44 ± 1.30	
BMI (kg/m ²)			
< 25	91	-1.95 ± 1.57	0.42
≥ 25	68	-1.75 ± 1.56	

HbA_{1c} glycosylated hemoglobin, BMI body mass index, SD standard deviation

receiving insulin treatment experienced a significantly greater negative impact of diabetes on QoL than patients without those factors.

Distribution of responses

The distribution of responses and the weights assigned to the impact rating are shown in Table 2. Diabetes had the greatest impact on freedom to eat as I wish (mean impact rating: -1.54 ± 0.95) and the least impact on living conditions (-0.56 ± 0.79). Family life (2.09 ± 0.73) and sex life (1.25 ± 0.93) were rated as the most and least important items, respectively. After being weighted (weighted impact score: impact multiplied by importance), freedom to eat (-3.27 ± 2.88) was still the most impacted QoL domain, while living conditions (-1.10 ± 1.81) was the least. Weighted mean scores for four items (local or long-distance journeys, family life, having close personal relationships, and financial situation) differed from the impact scores by more than three ranks. The weighted impact scores of these items (family life, having close personal relationships, and financial situation) became less negative, whereas that of local or long-distance journeys became more negative. No ceiling or floor effect was detected in total or item scores for any of the 19 items.

Factor structure and reliability of the JP-ADDQoL

The ADDQoL domain structure was examined by unforced factor analysis with promax rotation. The factor analysis extracted four factors with eigenvalues >1 (Table 3). The four-factor solution explained 60.8 % of the total variance. However, most of the items had high loadings on all four factors. Therefore, we examined the forced one-factor solution for the 19 items on the basis of the original ADDQoL. In these examinations, all factor loadings except sex life were >0.40 and explained 44.3 % of the total variance (the factor loading for sex life was 0.397). Cronbach's alpha coefficient, an index of the internal consistency of the scale, was 0.933, therefore indicating that the reliability of the JP-ADDQoL is more than adequate.

Validity of the JP-ADDQoL

JP-ADDQoL scores were highly correlated with PAID scores ($r = -0.442$, $P < 0.01$). To assess further the validity of the JP-ADDQoL, we conducted CFA. The structural equation model was used to evaluate the overall model fit: χ^2/df was 2.28; RMSEA, 0.090; GFI, 0.830; and CFI, 0.902, suggesting that the JP-ADDQoL achieved acceptable construct validity.

Table 2 Weighted impact scores and differences in ranks between unweighted and weighted means for the Audit of Diabetes-Dependent Quality of Life (JP-ADDQoL)

	Mean $\pm$ SD of weighted score	Ranks of impact	Ranks of importance	Ranks of weighted means ^a	Participants who assigned 0 value to importance (%)
1. Leisure activities	-2.10 ± 2.44	7	6	9	2.5
2. Working life	-1.95 ± 2.37	13	3	12	2.6
3. Local or long-distance journeys	-1.72 ± 2.35	5	18	14	17.7
4. Holidays	-2.29 ± 2.66	4	9	5	2.2
5. Physical health	-2.05 ± 2.24	9	11	11	3.8
6. Family life	-2.26 ± 2.70	12	1	7	1.9
7. Friendship and social life	-1.79 ± 2.19	14	5	13	3.2
8. Having close personal relationships	-2.46 ± 2.62	8	2	4	4.3
9. Sex life	-1.65 ± 2.56	15	19	15	24.1
10. Physical appearance	-1.17 ± 1.59	17	16	17	11.8
11. Self-confidence	-2.05 ± 2.39	10	12	10	8.2
12. Motivation	-2.29 ± 2.44	6	7	6	4.4
13. People's reaction	-1.14 ± 1.71	18	17	18	15.8
14. Feelings about the future	-2.91 ± 2.81	2	10	2	4.4
15. Financial situation	-2.12 ± 2.35	11	4	8	5.7
16. Living conditions	-1.10 ± 1.81	19	14	19	8.9
17. Dependence on others	-1.33 ± 1.94	16	15	16	9.5
18. Freedom to eat	-3.27 ± 2.88	1	8	1	3.2
19. Freedom to drink	-2.70 ± 2.77	3	13	3	7.6

SD standard deviation

^a Calculated by multiplying the score of impact by the score of importance

Table 3 Result of unforced factor analysis with promax rotation of the Audit of Diabetes-Dependent Quality of Life (JP-ADDQoL)

	Factor			
	1	2	3	4
12. Motivation	0.81	0.63	0.47	0.58
11. Self-confidence	0.80	0.50	0.48	0.47
13. People's reaction	0.74	0.56	0.53	0.65
14. Feelings about the future	0.74	0.52	0.61	0.49
6. Family life	0.72	0.60	0.43	0.57
8. Having close personal relationships	0.71	0.65	0.43	0.55
10. Physical appearance	0.61	0.44	0.26	0.56
9. Sex life	0.50	0.30	0.19	0.24
4. Holidays	0.69	0.93	0.52	0.56
3. Local or long-distance journeys	0.44	0.80	0.39	0.41
7. Friendship and social life	0.73	0.77	0.61	0.69
1. Leisure activities	0.55	0.76	0.44	0.46
5. Physical health	0.64	0.68	0.46	0.53
2. Working life	0.47	0.52	0.34	0.32
19. Freedom to drink	0.43	0.44	0.95	0.35
18. Freedom to eat	0.53	0.52	0.84	0.43
16. Living conditions	0.51	0.47	0.31	0.96
17. Dependence on others	0.51	0.44	0.50	0.67
15. Financial situation	0.57	0.51	0.60	0.61

Discussion

We are the first group to translate the ADDQoL, a common diabetes-specific QoL measurement scale, into Japanese (JP-ADDQoL). We also evaluated the validity and reliability of the JP-ADDQoL in Japanese patients with diabetes.

ADDQoL score trends were similar to those found in previous studies in terms of participants who had a high HbA_{1c} value [8], had diabetes complications [7, 8], or were receiving insulin treatment [7, 8, 11, 13], showing highly negative JP-ADDQoL scores. The differences in sex [8, 13] or age (young/old) [7, 13] were not significant. In particular, our trend for Japanese participants completely corresponded to findings of the Korean study [8]. On the other hand, Wee et al. [11] reported that among Asian participants (Chinese, Indians, and Malaysians), scores were significantly higher in women than in men. In our study, the trend was similar, although the difference was not significant. These results suggest that the JP-ADDQoL is culturally well adapted to Japanese patients with diabetes.

All domains showed a negative influence of diabetes on patients' QoL. The largest negative QoL impact and weighted impact on QoL observed in this study was freedom to eat, which was consistent with findings of previous studies [5, 6, 10–14]. The impact and weighted ranks for

sex life, which were not examined in other diabetes-related QoL questionnaires in Japan, were 15. However, a significantly marked difference was found between men and women: 43.3 % of the women answered that they do not or would not like to have a sex life, whereas 25.0 % of the men answered that they do or would like to have a sex life. In addition, 50.0 % of the women who provided responses to having a sex life or would like to have a sex life considered a sex life not to be important, whereas only 7.6 % of the men answered so. The average weighted impact score for sex life was -2.27 ± 2.88 for men and -0.50 ± 1.16 for women, showing a greater negative impact for men ($P < 0.01$). Therefore, we might have to examine not only the AWI score but also each weighted impact domain score to understand patients' views of their QoL.

The factor analysis and Cronbach's alpha showed satisfactory results. In particular, Cronbach's alpha for the JP-ADDQoL outperformed the original version [6], which adds to the strength of translation accuracy and cultural adaptation. In addition, the JP-ADDQoL and PAID scores were highly correlated, which shows that criterion-related validity was established. On the other hand, although the result of the structural equation model yielded an acceptable fit, such as that reported for some other questionnaires [26, 27], the result was not perfect. This imperfect result, despite the fairly high result for Cronbach's alpha, may be explained by the variability of participants' background characteristics, particularly the broad age range (18–82 years), even though the number of participants was relatively small.

To our knowledge, no questionnaires exist that evaluate both the impact and importance of diabetes in specific domains of life. In the JP-ADDQoL, rankings of four items greatly differed between impact score and weighted impact score, implying the necessity of examining both the impact and importance of specific domains.

Some limitations should be considered when interpreting our study results for the JP-ADDQoL. First, participants were from a single hospital in Japan. However, their characteristics (age: 59.7 ± 12.6 vs. 61.9 ± 11.9 years; BMI: 24.5 ± 4.5 vs. 24.0 ± 3.7 kg/m²) were similar to the characteristics of the participants in the Japan Diabetes Data Management Study Group (JDDM), which is a large cohort group comprising 16,934 patients from 61 hospitals [28]. Second, deficiencies in responses were relatively high: about 40 % occurred from failure to answer either impact or importance questions, probably through simple errors. Therefore, when collecting questionnaires, it should be confirmed that no blank spaces exist. Third, further study is required to confirm findings of CFA of the JP-ADDQoL in a large population, since this study population was small. Fourth, since patients' characteristics were

determined by responses within the questionnaire, the prevalence of complications according to this self-report could be lower than the actual prevalence of complications. However, the purpose of this study was to develop the JP-ADDQoL questionnaire, and we found higher scores among patients who perceived that they had a diabetic complication. Fifth, we evaluated reliability based only on Cronbach's alpha. However, the aim of this study was to develop a Japanese version of the ADDQoL, which means that the items on the ADDQoL did not originate with us. Reliability based on reproducibility (test–retest) was proved in a previous study [12].

In conclusion, we determined that the Japanese version of the ADDQoL (JP-ADDQoL) had satisfactory reliability and acceptable validity. Examining the impact of diabetes on a specific domain of life and its importance for each patient could lead to more accurate individualized QoL measurements in diabetic patients. Further studies are expected to confirm the validity of the JP-ADDQoL in a large and age- and sex-specific population.

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Compliance with ethical standards

Conflict of interest The authors declare that there is no duality of interest associated with this manuscript.

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