Original Article

Validation of the Malay version of Diabetes Quality of Life (DQOL) Questionnaire for Adult Population with Type 2 Diabetes Mellitus

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Abstract

Objective: We aimed to validate the Malay version of Diabetes Quality of Life (DQOL) questionnaire for Malaysian adult population with type 2 diabetes mellitus (DM).

Methods: This is a cross-sectional study to validate Malay version of DQOL among the adult diabetic patients. DQOL questionnaire has 46 items consist of three domains, namely Satisfaction Domain, Impact Domain and Worry Domain. Both forward and backward translations from the English version of DQOL into Malay version were performed. After the face validity of the Malay version was established, it was then pilot-tested. Finally, the validity and reliability of the final Malay version of DQOL questionnaire were evaluated.

Results: There were 290 patients participated in this study with a mean (SD) age of 53.1 (10.0) years. The Cronbach's alpha coefficients of the overall items and the main domains were between 0.846 and 0.941. The Pearson's correlation coefficients for the three domains were between 0.228 and 0.451. HbA1C was found to be positively correlated with Impact Domain (P = 0.006). The Worry Domain was associated with diabetic retinopathy (P = 0.014) and nephropathy (P = 0.033).

Conclusion: The Malay version of diabetes quality of life (DQOL) questionnaire was found to be a valid and reliable survey instrument to be used for Malaysian adult patients with diabetes mellitus.

Keywords: diabetes, validation, quality of life, questionnaire

Introduction

Diabetes mellitus (DM) and its complications pose a significant health threat in Malaysia. Based on the National Health and Morbidity Survey (NHMS) 2011, there are at least 2.6 million adult diabetic patients in Malaysia (1). Without proper medical intervention, diabetic patients could suffer from various diabetic complications in life. These long-term complications of diabetes mellitus can also have negative impact on the health outcomes and quality of life of the diabetic patients (2). The lifelong nature of each patient's diabetic condition can make it more challenging to manage this condition as time passes (3). In addition, the requirement of tedious diabetic self-care can lead to psychological problem like depression and affect their adherence to diabetic treatment. This can complicate further the diabetic control in this group of patients (4).

Clinical parameters (eg. glycemic control) are often used as means to assess the disease control and its clinical outcomes. However, the measure of quality of life is another more important aspect of the patient-reported outcome that should be emphasised. The quality of life (QOL) has been well-recognised as a useful criterion for evaluating medical treatment outcome along with the physiological measures of health status (5–7). Researchers often find it difficult to obtain a suitable survey instrument to assess quality of life, especially among diabetic patients. The DQOL questionnaire has been translated into Malay and validated. However, it is validated only in the Malaysian paediatric diabetic patients (8). Therefore, it is necessary to validate the Malay version of DQOL for the Malaysian adult diabetic patients (especially those having type 2 diabetes mellitus) as they constitute almost 97.5% of the total patient population in Malaysia (9).

DQOL questionnaire is one of the most widely used survey tool for assessing diabetic-specific quality of life (10). This questionnaire is a 46-item scale to measure the impact of medical intervention on quality of life in diabetic patients, which was developed in the early 1980's to be used for the Diabetes Control and Complication Trial (i.e. DCCT, a randomised controlled trial comparing the effect of two alternative treatment regimens on chronic diabetic complications in Type 1 DM for adult and adolescent diabetic patients) (11–15). It is developed to assess three main areas of patient-reported outcomes such as satisfaction with treatment, impact of treatment and worry about the future effects of diabetes (16).

DQOL questionnaire consists of three major domains such as (i) Diabetes Life Satisfaction Scale (QOL Satisfy) – 18 items, (ii) Disease Impact Scale (QOL Impact) – 27 items, and (iii) Disease Related Worries Scale (QOL Worry) – 14 items and a General Health Questionnaire (GHQ). The GHQ consists of only one question to provide a self-rating of overall general health. All items included in the Satisfaction Domain are scored on a five-point scale, ranging from 1 (very satisfied) to 5 (very dissatisfied) while all items included in both the domains on 'Impact' and 'Worry' are scored on a five-point scale, ranging from 1 (never) to 5 (all the time). A higher average score indicates a poorer QOL (16).

This instrument has been used in numerous studies in both Type I DM and Type 2 DM patients. It is easy to be administered and has

been demonstrated to be valid (14–15). From the findings of previous studies, a significant correlation exists between the total DQOL score and the number and severity of diabetic complications and the impact of different medical interventions for diabetes (17–18). DQOL questionnaire has been translated and validated into various languages such as Spanish, Turkish, Japanese, Chinese, Taiwanese and Iranian (17–22).

Since QOL is an important health outcome for diabetic patients, a validated Malay questionnaire to measure quality of life among diabetic patients is required, especially for Malaysian adult population. Hence, this study aimed to validate the Malay version of DQOL for Malaysian adult diabetic patient population.

Methodology

This study was registered with National Medical Research Registry (with registration number as NMRR ID:14-522-19377) and ethics approval was granted by the Medical Research & Ethics Committee (MREC). This cross sectional study was conducted on Malaysian adult diabetic patients of at least 18 years and above from Klinik Kesihatan Seremban 2, Negeri Sembilan.

The inclusion criteria were: (i) Malaysian diabetic patients of age 18 years and above, (ii) able to read and write in Malay language and (iii) diagnosed with DM (irrespective of the duration and type of anti-diabetic treatment given). The exclusion criteria were (i) patients with cognitive impairment (such as mental retardation and severe psychosis), (ii) unable to read and write in Malay (iii) having problems to listen and understand Malay language.

This study was conducted in three phases: Phase 1 involved translation of the original English questionnaire into its Malay version; Phase 2 involved pre-test of the Malay version of the questionnaire; and Phase 3 involved validation of Malay version DQOL among the Malaysian adult diabetic patients.

Phase 1: Translation Process

The translation was performed by two different groups of experts: the first group consists of experts in the subject matter (i.e. the medical personnel) and the second group consists of experts in language use (i.e. the linguistic personnel). First, two forward translations from English into Malay were performed by the first and second groups of

experts independently. Two different sets of Malay version DQOL questionnaire were obtained (i.e. version BM1, version BM2).

Next, two backward translations from Malay into English (i.e. version BI1, version BI2) were independently performed by another two different groups of experts who were totally unaware of the content of the original version of DQOL questionnaire. Subsequently, another two different English-translated versions were obtained. All four groups of experts worked independently during the translation process in this phase. An open discussion between these four groups of experts was held to consolidate all the four translated versions (i.e. BM1, BM2, BI1 and BI2). All discrepancies were reconciled to prepare the pre-final Malay version of this questionnaire in Phase I.

Pre-test

The face validity of the pre-final Malay version of DQOL questionnaire was evaluated during the pre-test. This step was to evaluate the responses obtained from respondents to determine their understanding on each question in the questionnaire correctly. This pre-test was conducted on a sample of 7 to 15 patients with diabetes mellitus from the same centre. After the respondents completed the questionnaire, they provided their feedback on their understanding on all the words and sentences in the questionnaire. The respondents also responded on their general understanding of the overall content of this questionnaire on a specific measurement scale. After the face validity of this questionnaire was assessed and found to be satisfactory, the Malay version of DQOL questionnaire would then undergo the final step of validation.

Validation

This final step of validating the Malay version of the DQOL questionnaire for Malaysian adult diabetic population involved testing its reliability and validity. All patients who fulfilled the inclusion criteria were approached to participate in the study. They were asked to provide a written consent prior to their participation in this study. All patients were given about 15–20 minutes to fill in the questionnaires. Each of these patients was given two questionnaires to fill, namely: (i) the questionnaire on patient's demographic information (i.e. age, gender, ethnicity, education, parents' education level, socio-economic status, marital status) and (ii) the final validated Malay version of the DQOL questionnaire.

Statistical Methods

The internal consistency of the final Malay version DQOL questionnaire was evaluated using Cronbach's alpha coefficient and the item-total correlation. The correlations among the three major domains (i.e. Satisfaction, Impact and Worry) and the correlations between the three major domains and HbA1c were evaluated using Pearson's correlation test. Association between diabetic complications (such as retinopathy, nephropathy, neuropathy and heart disease) and each of the three major domains was next analysed using the Analysis of Covariance (ANCOVA) test. The initial results obtained from ANCOVA test were then adjusted for potential confounders such as age, gender, race, education level and income. All the data were analysed using SPSS version 20.0 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp).

Results

A total of 290 patients participated in the validation study phase, with an almost equal proportion of the two genders (with 51% male). The mean (SD) age of all patients was 53.1 (10.0). Malay was the majority of these patients (69.7% of the total 290 patients), while Chinese and Indian were 7.6% and 22.8% respectively. Majority of these patients (64.2%) had attained secondary level of education or at least passed the general-certificate level as their highest level of education and their household income was almost equally distributed, with the majority (24.1%) earning RM1001 to RM 2000 (Table 1).

There were total of 36 patients participating in the pre-test phase. For the evaluation of the face validity of the Malay version of DQOL questionnaire, majority stated that they understood (72.2%) and were able to answer the questions (75.0%), while the remaining patients were unsure (Table 2). The mean (SD) for Satisfaction, Impact and Worry were 2.4 (0.9), 2.0 (0.5) and 1.2 (0.7) respectively. The Cronbach's alpha coefficient of the overall questionnaire was calculated to be 0.925 and the Cronbach's alpha coefficients of the three major domains were calculated to be between 0.846 and 0.941 (Table 3). The correlation coefficients

Table 1. Demographic characteristics of patients in the validation phase

Profile characteristics	Mean (SD)	n (%)
Mean Age (in years)	53.1 (10.0)	
Age group (year)		
< 30		5 (1.8)
30–60		215 (74.1)
> 60		70 (24.1)
Gender		
Male		148 (51.0)
Female		142 (49.0)
Ethnicity		
Malay		202 (69.6)
Chinese		22 (7.6)
Indian		66 (22.8)
Other		0 (0.0)
Marital status		
Married		250 (88.4)
Single		15 (5.3)
Divorce		8 (2.8)
Widow		10 (3.5)
Education level		
None		3 (1.0)
Primary school		12 (4.2)
Secondary school/ Certificate		183 (64.2)
Diploma/Bachelor		72 (25.3)
Master/Phd		15 (5.3)
Household income		
< RM 1000		56 (20.4)
RM 1001–RM 2000		66 (24.1)
RM 2001–RM 3000		50 (18.3)
RM 3001–RM 5000		63 (23.0)
> RM 5000		39 (14.2)

Table 2. Results based on the pre-test phase

Questions	n (%)
1. Saya memahami soalan soal selidik DQoL dengan baik *I understand the questions of DQoL questionnaire very well*	
Sangat tidak setuju *Not strongly agree*	0 (0.0)
Tidak setuju *Not agree*	0 (0.0)
Tidak pasti *Not sure*	10 (27.8)
Setuju *Agree*	17 (47.2)
Sangat setuju *Strongly agree*	9 (25.0)
2. Saya dapat menjawab semua soalan soal selidik DQoL mengikut kehendak soalan dengan baik *I can answer all the questions from DQoL questionnaire according to the requirement of the questions very well.*	
Sangat tidak setuju *Not strongly agree*	0 (0.0)
Tidak setuju *Not agree*	0 (0.0)
Tidak pasti *Not sure*	10 (27.8)
Setuju *Agree*	17 (47.2)
Sangat setuju *Strongly agree*	9 (25.0)

obtained from the three major domains were between 0.228 and 0.451 (Table 4).

HbA1c was found to be positively correlated with the Impact Domain ($P = 0.003$) (Table 5). In the univariate analysis, diabetes complications were associated with satisfaction and impact (Table 6). However, based on multivariate analysis, we did not have sufficient evidence ($P > 0.05$) to demonstrate the association between diabetic complications and the two

domains on Satisfaction and Impact. However, it was found that retinopathy had a sizeable effect (mean score of 2.0 from no retinopathy group versus 2.7 from retinopathy group, $P = 0.078$) on the Impact Domain, though its P-value was not statistically significant. Also, it was found that both retinopathy ($P = 0.014$) and nephropathy ($P = 0.033$) had positive associations with the Worry Domain (Table 7).

Discussion

The Malay version of DQOL questionnaire was found to be a reliable and valid survey instrument for Malaysian adult diabetic population. The study findings revealed that the Malay version of DQOL questionnaire has

Table 3. The descriptive statistics and reliability of the Malay version of DQOL

Domain	mean (SD)	min, max	Cronbach's alpha	Item-Total Correlation (Min, Max)
Satisfaction (n = 208)	2.4 (0.9)	1.0, 4.8	0.941	0.513, 0.818
Impact (n = 191)	2.0 (0.5)	1.3, 3.4	0.869	0.154, 0.662
Worry (n = 274)	1.2 (0.7)	0.0, 4.1	0.846	0.336, 0.707

Table 4. The Pearson correlation coefficient (*P*-value) among domains of the Malay version of DQOL

Domain	Satisfaction coefficient (*P*-value)	Impact coefficient (*P*-value)	Worry coefficient (*P*-value)
Satisfaction (n = 208)	1.000	0.259 (0.001)	0.228 (0.001)
Impact (n = 191)	0.259 (0.001)	1.000	0.451 (< 0.001)
Worry (n = 274)	0.228 (0.001)	0.451 (< 0.001)	1.000

Table 5. The Pearson correlation between the domains scores of the Malay version of DQOL and HbA1c

Domain	HbA1c	
	r	*P*-value
Satisfaction	0.04	0.546
Impact	0.22	0.003
Worry	0.05	0.438

an excellent internal consistency and validity for Malaysian adult diabetic population. This is consistent with other previous studies which had validated the translated versions of DQOL questionnaire in Chinese, Turkish, Iranish and Spanish populations (17–18, 20–22)

The evaluation of the face validity of DQOL questionnaire had shown that most patients could understand this questionnaire easily. Attaining a satisfactory level of face validity is an important criterion of a valid questionnaire, because this will enable us to draw valid responses from the respondents. In addition, the Malay version of DQOL questionnaire also had reported an excellent level of internal consistency within each domain. Every question within the same domain will be measuring the same item for all Malaysian adult diabetic patient population.

Besides that, the validity of the Malay version DQOL questionnaire was further confirmed by the following findings: (i) a degree of correlation is found between the three major domains, (ii) a positive correlation is found between Impact Domain and HbA1c, (iii) an association exists between diabetic complications and Worry Domain. The association between a clinical outcome and a measure of patient-reported quality of life is crucial to reflect the impact of the clinical outcomes on patient-reported quality of life.

We found that there was a degree of correlation between the three major domains, and these results were consistent with those from the original study even though the coefficients we obtained were slightly lower. Our results indicated that the three domains were found to be independent of each other because the degree of correlation between them was not high (a very high degree of correlation shows that the domains are measuring the same aspect of an item). Secondly, low to moderate degree of correlations found between the three domains indicated that there was still a relationship in between them. This finding is expected in this case because the three domains are actually measuring the same dimension of the patient-reported quality of life.

The validity of Malay version of DQOL can also be assessed based on the evidence of any association between HbA1c and the three major DQOL domains. A major shortfall of our study finding was that the associations between HbA1c and three major QOL domains still remain controversial as the association was only found to be statistically significant between HbA1c and Impact Domain. A previous study reports that an improvement in HbA1c was associated with

Table 6. The association between the domains scores of the Malay version of DQOL and diabetes complications; a univariate analysis based on independent sample *t*-test

Domain	Complications	Mean (SD)	*t*-statistics (*df*)	*P*-value
Satisfaction	Retinopathy			
	Yes	2.3 (0.47)	-0.33 (206)	0.746
	No	2.4 (0.87)		
	Nephropathy			
	Yes	2.2 (0.86)	-0.54 (206)	0.594
	No	2.4 (0.86)		
	Neuropathy			
	Yes	2.6 (0.14)	2.69 (9)	0.024
	No	2.4 (0.87)		
	Heart disease			
	Yes	2.4 (0.79)	0.11 (206)	0.912
	No	2.4 (0.87)		
Impact	Retinopathy			
	Yes	2.7 (0.32)	2.99 (189)	0.003
	No	2.0 (0.46)		
	Nephropathy			
	Yes	2.0 (0.65)	-0.13 (189)	0.894
	No	2.0 (0.47)		
	Neuropathy			
	Yes	2.3 (0.26)	1.02 (189)	0.311
	No	2.0 (0.47)		
	Heart disease			
	Yes	2.0 (0.35)	-0.58 (189)	0.565
	No	2.0 (0.48)		
Worry	Retinopathy			
	Yes	1.9 (0.89)	2.94 (272)	0.004
	No	1.2 (0.64)		
	Nephropathy			
	Yes	1.4 (1.28)	0.36 (5)	0.732
	No	1.2 (0.64)		
	Neuropathy			
	Yes	1.1 (0.37)	-0.29 (272)	0.772
	No	1.2 (0.66)		
	Heart disease			
	Yes	0.8 (0.30)	-2.15 (272)	0.033
	No	1.2 (0.67)		

a short-term improvement in QoL, while several other studies show no association (23–26).

From this study, we found out that HbA1c (in continuous numerical value) was not associated with quality of life (i.e. satisfaction and worry). This is probably because these two domains for patient-reported quality of life are not solely dependent on HbA1c. Patients with poor glycaemic control might still have a good QOL if they have yet to experience any diabetic complications. Likewise, not all diabetic patients will have a psychological problem (27) which is measured by the Worry Domain about future consequences of diabetic condition.

Table 7. The association between the domains scores of the Malay version of DQOL and diabetes complications; a multivariate analysis based on Analysis of Covariance (ANCOVA)

Domain	Complications	Marginal mean (SE)	F-statistics	P-value
Satisfaction	Retinopathy			
	Yes	2.7 (0.55)	0.01	0.905
	No	2.6 (0.35)	(1, 180)	
	Nephropathy			
	Yes	2.6 (0.52)	0.02	0.903
	No	2.7 (0.41)	(1, 180)	
	Neuropathy			
	Yes	2.7 (0.54)	0.05	0.825
	No	2.6 (0.38)	(1, 180)	
	Heart disease			
	Yes	2.7 (0.50)	0.10	0.751
	No	2.6 (0.38)	(1, 180)	
Impact	Retinopathy			
	Yes	2.7 (0.31)	3.15	0.078
	No	2.3 (0.22)	(1, 162)	
	Nephropathy			
	Yes	2.5 (0.33)	0.06	0.807
	No	2.5 (0.22)	(1, 162)	
	Neuropathy			
	Yes	2.6 (0.33)	1.14	0.287
	No	2.3 (0.20)	(1, 162)	
	Heart disease			
	Yes	2.5 (0.27)	0.07	0.788
	No	2.5 (0.23)	(1, 162)	
Worry	Retinopathy			
	Yes	1.8 (0.31)	6.12	0.014
	No	1.2 (0.22)	(1, 240)	
	Nephropathy			
	Yes	1.9 (0.32)	4.59	0.033
	No	1.2 (0.25)	(1, 240)	
	Neuropathy			
	Yes	1.4 (0.35)	0.56	0.454
	No	1.7 (0.22)	(1, 240)	
	Heart disease			
	Yes	1.4 (0.31)	1.32	0.252
	No	1.7 (0.23)	(1, 240)	

Results were derived after controlled for age, gender, race, education level and income

On the other hand, the respondent-reported QOL measures depend entirely on how they have responded to their diabetic conditions. Lazarus and Folkman's theory (1984) stated that an emotional response shall result from the person's interpretation of both the event and his/her ability to cope with it, rather than directly from the occurrence of an event (28). Therefore, the quality of life of a diabetic patient is often adversely affected once he/she starts to experience a diabetic-related complication especially if he/she is unable to

cope with the complication. This is well proven by previous studies which had found that diabetic complications pose a significant impact on quality of life (29–32). This explains the significant association between the HbA1c and the domain of impact in our study.

The third basis for assessing the validity of Malay version DQOL questionnaire is the association between QOL and diabetic complications. From our study, we found that diabetic complications adversely affect the patient-reported QOL. The domain on worry about future consequences of diabetic condition was found to be positively associated with diabetic retinopathy and nephropathy. This means that presence of diabetic complications such as diabetic retinopathy and nephropathy increases patient's feeling of worry about future consequences of diabetic condition, which in turn adversely affects the patient-reported QOL. However, other diabetic complications were not found to be associated with the three major domains of patient-reported QOL. Overall, this finding is consistent with other studies whereby the presence of diabetic neuropathy and retinopathy had been revealed to be associated with reduced health-related quality of life (32–34).

All in all, this study had specifically validated this Malay-translated version of the DQOL questionnaire for Malaysian adult diabetic population. It can potentially be a very useful tool for all clinicians and researchers to measure the three different domains of patient-reported quality of life (i.e. Satisfaction, Impact and Worry) for the Malaysian adult diabetic patient population in the future. This survey instrument had already been adapted and used in many previous clinical studies (35–39), and proven to be both a valid and reliable questionnaire in others populations. However, this DQOL questionnaire is a disease specific quality of life questionnaire which is only limited to three domains and hence, it is recommended that researchers may also consider to use other general quality of life questionnaire such as 36-Item Short Form Health Survey (SF-36) in addition to DQOL questionnaire so that other aspects of quality of life can be measured (40).

Nevertheless, this study has some limitations. The test-retest reliability of this questionnaire had not been evaluated. In addition, according to the findings obtained from this study, we found that the DQOL questionnaire contains too many items, and it is time consuming for patients to complete DQOL questionnaire. It is likely for the older diabetic patients especially those having suffered from diabetic complications might face difficulty in answering all the questions in this DQOL questionnaire.

In summary, this translated Malay version of the DQOL questionnaire had been found to be a reliable and valid survey instrument to measure patient-reported QOL in Malaysian adult diabetic patients because it had been evaluated for use in this specific patient population. Results from this study had also established that it has a strong level of internal consistency and sufficient evidences from validity such as content validity, face validity and the association with HbA1c and diabetes complications. Additional quality of life questionnaires may need to be considered especially when researchers aim to investigate domains or that are not captured by DQOL questionnaire.

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Authors' Contributions

Conception and design: MAB, MI
Analysis and interpretation of the data: MAB, NB
Drafting of the article: MAB, SHO
Critical revision of the article for important intellectual content: MAB, MI, NKBMH, SHO, NB, SSML
Final approval of the article: MAB, MI, NKBMH, SHO, NB, SSML
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Statistical expertise: MAB, NB
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