THE RELIABILITY AND VALIDITY OF THE MALAY VERSION OF THE 18-ITEM AUDIT OF DIABETES DEPENDENT QUALITY OF LIFE (THE MALAY ADDQOL) QUESTIONNAIRE

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Abstract. The objective of this study was to examine the reliability and validity of the Malay version of the 18-item Audit of Diabetes Dependent Quality of Life (the Malay ADDQOL). Patients with type 2 diabetes mellitus who fulfilled the inclusion criteria were systematically selected. The Malay ADDQOL linguistically validated from the 18-item English version ADDQOL was self-administered twice at a 1-week interval. Two hundred eighty-eight respondents were included in the study. Analysis involved checking the feasibility, floor and ceiling effects, internal consistency, test-retest reliability and factor analysis. Item means and standard deviations fulfilled the Likert scale assumptions. The Cronbach's alpha was 0.943 (lower bound of the 95% CI of 0.935) and the intraclass correlation coefficient was 0.81 (95% CI from 0.72 to 0.87). Exploratory one factor analysis showed factor loadings above 0.5 for all the 18 items. The Malay ADDQOL has acceptable linguistic validity. It is feasible, has excellent reliability, content, construct validity, and is recommended to be used among Malay-speaking diabetic patients.

INTRODUCTION

There is increasing recognition that the impact of chronic illnesses and their treatments must be assessed in terms of their influences on quality of life in addition to more traditional measures of medical outcome, such as morbidity and mortality. Health related quality of life is an example of an increasingly used outcome measure in clinical trial research (Fayers and Machin, 2000) to complement these traditional measures. In recent years, the quality of life, consisting of physical, psychological and social aspects, has become more important in health care (Bradley *et al,* 1999). The usage of health related quality of life measures in many studies is supported from findings that subjective health was a better predictor of survival than measures objective health (Knauper and Turner, 2003). However, in assessing the impact of complications or treatments on the quality of life, it is important to utilize pure quality of life measures not health status measures because conclusions may be misleading (Bradley, 2001).

Condition-specific quality of life instruments are designed to address specific issues of the illness because generic instruments may be insensitive to small but clinically meaningful differences. This is the reason why condition-specific instruments are being developed to address this weakness. They can measure specific goals and end-points not evaluated by generic measures (The DCCT Research Group, 1988).

Brief instruments are desirable. They should also provide sufficient details so that better decisions can be made. For example,

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they can help in comparing different therapy modalities, assist in decision making in day to day clinical practice, and good quality instruments possess very high levels of validity and internal consistency (Streiner and Norman, 1989; Osoba, 1998; Garrat *et al,* 2002).

In study of the quality of life of diabetic patients, there are a considerable number of patient-assessment measures. This may create confusion for clinicians and researchers who are interested in measuring the quality of life of their patients but are having difficulty in choosing the best quality of life instrument. Based on the supporting evidence, the Audit of Diabetes Dependent Quality of Life (ADDQOL) (Bradley *et al,* 1999; Bradley and Speight, 2002), Diabetes Health Profile (DHP-1, DHP-18), Diabetes-Specific Quality of Life Scale (DSQOLS), Diabetes-39 (D-39) and Diabetic Patients-revised (QSD-R) offer the most promising approaches (Garrat *et al,* 2002).

The aim of our study was to determine the reliability and validity of the Malay version of the 18-item Audit of Diabetes Dependent Quality of Life (The Malay ADDQOL). The ADDQOL was designed to cover broad aspects of life likely to be influenced by diabetes. Users or respondents are also permitted to indicate whether potentially affected domains of life apply to them and to rate their impact together with the perceived importance of each domain for their quality of life (Bradley and Speight, 2002) which make this questionnaire unique in relation to others.

The validation of the disease-specific instrument, the Malay version of the 18-item ADDQOL (the Malay ADDQOL) would make one diabetes-specific instrument available for researchers dealing with Malay-speaking diabetic patients in local and regional settings. The results from evaluation using the Malay ADDQOL in diabetic patients in local settings can be compared with other ADDQOL results elsewhere. Any differences may reflect "shortfalls" or "better performance" in quality of life. Of course this may reflect the effectiveness of interventional programs, public health programs and may even provide the basis for action, whether immediately or in the long run (Abramson and Abramson, 1999; Azman *et al,* 2003). Malay speaking diabetic patients especially from Southeast Asian countries like Malaysia, Indonesia, Singapore and parts of Thailand and Philippines would likely be benefit from the accessibility of the questionnaire.

MATERIAL AND METHODS

Design and selection of respondents

We carried out a cross-sectional study in patients with type 2 diabetes mellitus. The study was conducted at the four diabetes clinics from May 2004 to May 2005. The study was approved by the Research and Ethics Committee of the School of Medical Sciences, Universiti Sains Malaysia, Malaysia.

To select the patients we employed the list of diabetic patients registered from four clinics for diabetes as the sampling frame and systematic sampling was used as the sampling method.

Inclusion and exclusion criteria

The inclusion criteria for the study were that the patients had been diagnosed with Type 2 diabetes mellitus for at least 1 year before the commencement of the study, eighteen years (18) of age or older and were able to read and write in the Malay language. All the respondents included in the study were given a complete informed consent form. The Research and Ethics Committee of the School of Medical Sciences, Universiti Sains Malaysia, had reviewed it earlier. The researchers were present to answer any questions pertaining to the informed consent. The respondents signed the informed consent form if they agreed to participate in the study.

We excluded patients with cognitive impairment, substance abuse disorders, severe illness, or with co-morbidities not directly re-

lated to diabetes mellitus evidenced from medical records or personal declaration.

Sample size

A crucial step in a reliability study is the determination of the required sample size (Streiner and Norman, 1989; Bonett, 2002; Charter, 2003). The sample size of internal consistency for the Cronbach's alpha was calculated in an iterative process (Naing and Winn 2004, unpublished) using the Intercooled Stata 7.0 for Windows software (StataCorp LP, College Station, TX, USA) and derived from;

$\alpha_X \geq 1 - [(1- \alpha_X) F_{\alpha,n-1,(k-1)(n-1)}] = \alpha_L$ (Bleda and Tobias, 2001)

where k or the number of items of the ADDQOL was 18, α_x or the point estimate of the Cronbach's alpha was 0.84 from a study elsewhere (Jacobson *et al,* 1994), the α error was 0.05 and $F_{\alpha,n-1,(k-1)(n-1)}$ was 1.156. We have determined that the margin of error as 0.025, and therefore the lower bound should be at 0.815. Using the parameters the sample size needed with a non-response of 20%, was 304. One of the authors, L Naing wrote the program code and readers who are interested can obtain it from the corresponding author.

Tools

A group of our experts identified by the main researcher in our study carried out linguistic validation of the Malay ADDQOL from the original 18-item English ADDQOL version. They consisted of linguists, epidemiologists, physicians and medical doctors. The process of translation was carefully planned to ensure the preservation of the contents and the meanings (Euroqol Groups, 2001). The first stage involved two independent forward translations from English into Malay followed by two independent back-translations from Malay to English. Nine people including six Type 2 diabetes mellitus patients who were native speakers of Malay and three medical practitioners who were fluent in both Malay and English involved in the respondent testing or cognitive debriefing. The final stage included a review of feedback from the participants of the respondent testing. At each stage, an epidemiologist and an endocrinologist, who are experts in diabetes at our center reviewed the quality of the translations and made any necessary recommendations. After improvement of the questionnaire, the third or final consensus was produced and utilized.

Test-retest

We administered the Malay ADDQOL twice, *ie* during the selection of patients and one-week later. For the second administration, we chose 76 patients randomly selected from the first group of patients as practiced elsewhere (Unal *et al,* 2001).

The scores of each individual's instrument were then collected and the correlation between the test scores and retest scores was examined (Robert and Paul, 1993). We chose a shorter interval to avoid larger numbers of dropouts which could compromise the results.

Statistical analysis

To assess the feasibility of the Malay ADDQOL, we examined the frequency of floor effects or the number with the lowest possible score and ceiling effects or the number of respondents with the highest possible score (Osborne *et al,* 2003).

The internal consistency reliability coefficient using Cronbach's alpha or scale reliability coefficient (Bland and Altman, 1986) and the test-retest reliability using the intraclass correlation coefficient with absolute agreement, single rater and one way random effects model (people effect random) (Neter *et al,* 1996; Prieto *et al,* 1997) from SPSS 11.0.1 for Windows software (SPSS Inc, Chicago, Illinois, USA) were examined. The intraclass correlation coefficient was evaluated instead of the Pearson's product moment correlation (Bland and Altman, 1986; Kuo, 1994).

The construct validity of the Malay ADDQOL was evaluated using factor analy-

sis. During the analysis, Principal Component Analysis (PCA) with Varimax factor rotation was used for data extraction (Green *et al,* 1999; SPSS Inc, 2002). We performed a single factor extraction as we suspect the Malay ADDQOL would form only a single theoretical construct (Bradley *et al,* 1999; Bradley and Speight, 2002).

RESULTS

Patients

Two hundred and eighty-eight respondents were enrolled. Six patients were excluded from the study. Three of them suffered from liver failure, hyperthyroidism and severe joint disease. Two suffered from minor strokes and another one had major depression. There were 176 (61.1%) men and 112 (38.9%) women, the patient's characteristics are presented in Table 1. A descriptive evaluation of the summated ratings scale is shown in Table 2.

A clear explanation of the importance of the study helped to minimize missing data to less than 1.7%. We also made the effort to recheck the questionnaire when handed in by the patients. Any missing responses were noted and the patients were asked to fill in the missing sections. The means and standard deviations of the items and domains fulfilled the Likert's scale assumptions. There were 1.4% of the patients who had the lowest score, the floor effect or the "average weighted impact of the Malay ADDQOL" which equalled -9 and nobody had a maximum score, the ceiling effect or "the average weighted impact of the Malay ADDQOL" which equalled +9.

Reliability

The Cronbach's alpha or scale reliability coefficient for the average weighted Malay ADDQOL was 0.943 with a lower bound one-sided 95% confidence interval (CI) at 0.935. Values bigger than 0.85 can be considered acceptable and indicates all the 18 items in the Malay ADDQOL address the same underlying dimensions, in our case, the quality of life of diabetic patients. The Cronbach's alpha with each of the 18 items deleted is shown in Table 2.

The intraclass correlation coefficients (ICC) for the single rater using the one way analysis of variance (ANOVA) model was 0.81 with 95% CI ranging from 0.72 to 0.87. It suggests that the Malay ADDQOL is reproducible and possessed good agreement on two occasions separated by a one-week interval of time.

Validity

Exploratory factor analysis using Principal Component Analysis extraction and Varimax rotation initially produced two components or factors with Eigen values greater than one as seen in Table 3. The first factor loading had the 18 items loaded from 0.65 to 0.83 and consisted of all domains except items 16, 17 and 18 which are related to diets that loaded well on the second factor. The single factor using exploratory one factor analysis extraction revealed all 18 items loaded above 0.5 with the lowest of 0.52 for item

Table 1
Patients characteristics.

Profiles	Men	Women
	Means (SD)[a]	Means (SD)
Age (years)	52.67 (8.42)	51.13 (8.53)
Duration of diabetes (years)	8.70 (6.18)	7.61 (6.44)
HbA1c (%)	8.83 (2.45)	9.11 (2.47)
	n (%)	n (%)
Presence of complications	62 (23.3)	21 (7.9)
No complications	103 (38.7)	86 (30.1)
On diet or 1 oral ADA[b]	58 (21.8)	40 (15.0)
On 2 oral ADA	79 (29.7)	49 (18.4)
On 2 oral ADA or insulin or both	28 (10.5)	12 (4.5)
HbA1c ≤ 7.5%	41 (23.2)	19 (10.7)
HbA1c > 7.5%	67 (37.9)	50 (28.2)

[a]SD=standard deviation; [b]ADA=Anti diabetic agents

Table 2
Individual weighted impact scores for the Malay ADDQOL.

	Life domain	Missing (%)	Means (SD)	Corrected item-total correlation	Alpha if deleted	Cronbach's alpha (95% CI)
	Present QOL	0.0	0.85(0.87)			
	Diabetes dependent QOL	0.0	2.06(0.76)			
1.	Working life and work related opportunities	1.7	-5.76(2.72)	0.616	0.941	
2.	Family life	1.0	-5.25(2.91)	0.691	0.940	
3.	Friendships and social life	0.7	-4.50(2.99)	0.728	0.939	
4.	Sex life	1.7	-4.74(2.94)	0.595	0.941	
5.	Physical appearance	0.0	-4.69(2.85)	0.738	0.939	
6.	The things I can do physically	0.0	-4.88(2.86)	0.756	0.938	
7.	Holidays and leisure activities	0.7	-4.45(2.96)	0.783	0.938	
8.	Ease of travelling (local or long distance)	0.7	-4.58(2.98)	0.762	0.938	
9.	Confidence in ability to do things	0.7	-4.44(2.82)	0.783	0.938	
10.	Motivation to achieve things	1.0	-4.38(2.87)	0.769	0.938	0.943
11.	The way society reacts to me	0.7	-2.88(3.09)	0.653	0.940	(0.935,0.943)
12.	Worries about the future	0.7	-4.04(3.09)	0.602	0.941	
13.	Finances	0.7	-3.64(3.22)	0.714	0.939	
14.	Unwanted dependence on others	0.7	-3.33(2.93)	0.689	0.940	
15.	Living condition	0.3	-5.20(3.00)	0.674	0.940	
16.	Freedom to eat as I wish	0.3	-4.61(2.86)	0.538	0.942	
17.	Enjoyment of food	0.0	-4.36(2.82)	0.552	0.942	
18.	Freedom to drink as I wish	0.0	-4.00(2.90)	0.515	0.943	

number 18 and the highest 0.83 for item number 7. The lowest loadings were still from the related diet (item numbers 16, 17 and 18) as shown in Table 3.

DISCUSSION

The Malay ADDQOL showed an excellent Cronbach's alpha or scale reliability coefficient of 0.943 (lower bound of 95% CI of 0.935) indicating good internal consistency of the test instrument (Weiner and Stewart, 1984). This was probably due to a large number of items in the Malay ADDQOL. A Cronbach's alpha of 0.70 or 0.80 suggests excellent internal consistency (Ware *et al,* 1993; Nunnally and Berstein, 1994; Warschburger *et al,* 2003). Such a high Cronbach's alpha warrants toning down of some items. However, we decided to keep all 18 items because they capture important and unique aspects of diabetes.

For group comparison, our lower value of Cronbach's alpha was acceptable. Table 2 indicates all items had an acceptable corrected item-total correlation and a Cronbach's alpha when the domain deleted was also high.

The Malay ADDQOL has excellent absolute agreement with the exact intraclass correlation coefficient (ICC) of 0.81 exceeding 0.5 as required (Streiner and Norman 1989). This study is perhaps the first documentation of the test-retest reliability of ADDQOL.

We did respondent testing on nine people, including six people with type 2 diabetes mellitus and three medical practitioners, to establish the face validity. During development of the English version of ADDQOL, interviews with panels of experts and with adults having diabetes were done. The questionnaire

Table 3
Factor loadings from exploratory and exploratory one-factor analysis on the individuals' weighted impact score of the Malay ADDQOL.

	Exploratory		Exploratory one-factor
Domains	Component 1	Component 2	Component 1
Holidays and leisure activities	0.687	0.100	0.83
Confidence in ability to do things	0.759	0.119	0.82
Motivation to achieve things	0.804	0.102	0.81
The things I can do physically	0.640	0.153	0.80
Ease of travelling (local or long distance)	0.786	0.168	0.80
Physical appearance	0.749	0.281	0.78
Friendships and social life	0.779	0.281	0.77
Finances	0.753	0.289	0.75
Family life	0.790	0.253	0.73
Unwanted dependence on others	0.772	0.255	0.72
Living condition	0.705	0.143	0.71
The way society reacts to me	0.535	0.371	0.70
Sex life	0.713	0.256	0.66
Working life and work related opportunities	0.657	0.309	0.65
Worries about the future	0.653	0.289	0.65
Enjoyment of food	0.220	0.855	0.59
Freedom to eat as I wish	0.227	0.870	0.55
Freedom to drink as I wish	0.181	0.888	0.52

were also reviewed by the British Diabetic Association/Royal College of Physicians Working Group to ensure the content validity (Bradley *et al,* 1999). We subjected The Malay ADDQOL to further review by an experienced endocrinologist and a diabetologist at our center for a second opinion and potential issues concerning our local diabetic patients. However, both agreed with the content validity of the Malay ADDQOL.

The initial exploratory factor analysis extracted and rotated the 18 items into two large components. Fifteen items were in one component and three other items were in another component. The three items were item 16 (freedom to eat domain), item 17 (enjoyment of food domain) and item 18 (freedom to drink domain). When we proceeded to exploratory one factor analysis, as suggested by the author of the English ADDQOL (Bradley and Speight, 2002), all the items loaded satisfactorily, well above 0.5, reflecting the strong and obvious correlation structure of the single dimension of the Malay ADDQOL. This result is also consistent with the findings of the original English version of the 18-item ADDQOL (Bradley and Speight, 2002). We are of the same opinion with the author of English version ADDQOL that the ADDQOL contains only single factor extraction or single theoretical construct with no additional theoretical construct. Item 16 "Freedom to eat as I wish", was not the lowest score on the Malay ADDQOL compared to the English ADDQOL (Bradley and Speight, 2002). This is probably due to different characteristics in the lifestyle and socio-cultural expectations between the Malay patients and the English patients. However, future studies may be necessary to explain the difference.

Alternatively, researchers can use structural equation modelling (SEM) instead of factor analysis. But we, however performed factor analysis because of the unavailability of SEM software, such as AMOS or LISREL. We advise readers to use SEM whenever possible.

We are aware that during linguistic validation, there is neither one qualitative nor quantitative step that is sufficient to ensure a valid translation (Bullinger *et al,* 1998). The translation of ADDQOL into Malay was planned as carefully as possible with potential limitations in mind. The purpose of the linguistic validation of the Malay ADDQOL was to produce a good translation with the preservation of the content and the concept of the original English version of the ADDQOL. During the process, we utilized forward and backward translation and respondent testing before production of the final Malay ADDQOL (Euroqol Groups, 2001). We hope these measures ensure good quality translation.

We suggest researchers to use a standard translation guideline available from established groups, such as the EuroQol group (Euroqol Groups, 2001). We were informed that the translation guidelines for the ADDQOL are available from the original author. Interested readers may communicate with the author to obtain the guidelines and to apply them in the translation process. Ideally, the people doing the back translation should be native English speakers, however, we were not able to do this. Instead, an experienced linguist fluent in both Malay and English with a qualification in translation was involved in the process.

In conclusion, the Malay version of the 18-item Audit of Diabetes Dependent Quality of Life (the Malay ADDQOL) questionnaire has fulfilled the Likert's scale assumptions, has excellent internal consistency, repeatability and showed evidence of good construct validity and face validity. It has undergone acceptable linguistic validation and is feasible for use in diabetic patients. We recommend use of the Malay ADDQOL in measuring the quality of life of Malay speaking patients with diabetes mellitus.

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Readers who are interested in obtaining The Malay ADDQOL may communicate with Professor Clare Bradley, Head of Health Psychology the Department of Psychology, Royal Holloway University of London, Egham, Surrey, TW20 0EX (E-mail: C.Bradley@rhul.ac.uk Tel: 01784 443708).

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