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WHOQOL-BREF among Singaporean Patients with Type II Diabetes Mellitus: What Does It Measure?

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Authors' contributions

Author TAN Luor Shyuan Maudrene performed the statistical analysis and wrote the first draft of the manuscript. Author Bautista Dianne Carrol Tan performed the statistical analysis and managed the analyses of the study. Authors KHOO Eric Yin Hao, GRIVA Konstadina, LEE Yung Seng and WEE Hwee Lin wrote the protocol and designed the study. Authors Michelle New and Mohammad AMIR recruited subjects, conducted data entry and data checking. Authors LEE Jeannette and TAI E Shyong provided expert opinion on the study. All authors read and approved the final manuscript.

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ABSTRACT

Original Research Article

Aims: Health-related quality of life (HRQoL) of Type 2 diabetes mellitus (T2DM) is a growing concern globally given the increase in T2DM prevalence. Generic HRQoL

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instruments are important to allow cross-cultural, cross-population and cross-study comparisons. The short version of the World Health Organization Quality of Life (WHOQOL-BREF) questionnaire is a widely used generic questionnaire. Hence, we aimed to evaluate the psychometric properties of the WHOQOL-BREF among patients with T2DM in Singapore.

Study Design: Patients at a diabetes outpatient specialist clinic in Singapore were recruited via convenience sampling. Classical Test Theory methods were used to evaluate data quality, scaling assumptions, targeting, internal consistency reliability and construct validity (structural, convergent and discriminant) and criterion validity using HbA1c control (good versus poor). Principal Component Analyses (PCA) and Confirmatory Factory Analyses (CFA) were performed to assess unidimensionality (domain-level) as well as conformity with the original four-factor structure. Exploratory Factor Analysis (EFA) was done if CFA indicated lack of fit.

Results: 212 subjects were analyzed of whom 50% were Chinese, 28% Indians, 11% Malays and 10% others. 63% were males with mean (SD) age 45.8 (11.9) years. Data quality was superior, scaling assumptions were met, targeting was satisfactory and internal consistency was achieved. PCAs were compatible with unidimensionality, except in the Physical domain. Domain level CFA indicated that unidimensionality had poor fit and overall CFA did not support the original 4-factor structure. EFA runs showed that the Physical and Environment domains overlapped while the Social and Psychological domains could not be recovered. Therefore construct (structural) validity was not established. Criterion validity was not achieved as all domains could not discriminate between those with good versus poor HbA1c control.

Conclusion: Construct and criterion validity of WHOQOL-BREF posed some concerns. Thus, we recommend that an adequately-powered random sample of T2DM patients in Singapore be studied to confirm the findings of our study.

1. INTRODUCTION

Health-related quality of life (HRQoL) has become an increasingly important topic in patients with type 2 diabetes mellitus (T2DM) because it is a chronic disease that can lead to a multitude of complications associated with significant morbidity and mortality [1,2]. Furthermore, a large part of the treatment is focused on self-management, which requires constant monitoring, diet change and lifestyle modifications [3]. As such, the impact of T2DM on HRQoL is considerable [4,5]. Most importantly, the prevalence of T2DM is escalating locally [6,7] and globally [8] and is a major public health issue [9].

Generic HRQOL instruments are useful in that they can be used in cross-cultural, crosspopulation, and cross-study comparisons [10]. In addition, generic HRQoL instruments are invaluable in population-based surveys allowing for comparison in populations with or without the disease condition and between populations in different countries and tracking this over time. Some commonly used generic HRQoL instruments include the Sickness Impact Profile, Nottingham Health Profile, the Quality of Well-Being Scale, the Medical Outcomes Study 36-Item Short-Form Health Survey, and the World Health Organization Quality of Life (WHOQOL-100) assessment and its short version (WHOQOL-BREF).

Keywords: Diabetes mellitus; reliability; validity; health-related quality of life; quality of life; Singapore; Asia.

The WHOQOL-BREF, a 26-item questionnaire measuring four domains of HRQoL (physical health, psychological, social relationships and environment), has been developed as a shorter alternative to the WHOQOL-100 to provide a brief but accurate assessment of the quality of life [11]. We chose to evaluate the psychometric properties of WHOQOL-BREF for Singaporean patients with T2DM for three reasons. First, the WHOQOL-BREF assesses financial issues, which was ranked top in terms of relevance and importance to patients with T2DM in a focus group study conducted in Singapore (manuscript submitted). Second, the WHOQOL-BREF is royalty-free and would be more accessible to clinicians and researchers who may not have the necessary funds to pay for the use of copyrighted questionnaires. Third, although several studies in Singapore had used the WHOQOL-BREF among patients with schizophrenia [12,13], in pathological gambling [14] and to study resilience in youths [15], the psychometric properties of WHOQOL-BREF has not been formally evaluated in the Singapore population. Thus, the aim of our study was to determine the validity and reliability of the WHOQOL-BREF in a multi-ethnic population diagnosed with T2DM in Singapore.

2. METHODS

2.1 Study Design and Participants

This is a secondary analysis of the baseline data of a prospective longitudinal study on outcomes from a convenience sampling of patients with diabetes mellitus. This study was approved by the National Healthcare Group Domain Specific Review Board. English literate patients aged between 21 and 65 years old, who were diagnosed with diabetes (both Type 1 and Type 2) for at least one year, were recruited from the specialist outpatient clinic of the National University Hospital from 2011 to 2013. Patients were excluded if there was self-reported or documented unstable and ongoing treatment of heart, kidney, liver and psychiatric conditions or if they had gestational diabetes. The study terms and procedures were explained and written informed consent was obtained from all recruited patients. In the analysis, we only presented data on T2DM patients (Fig. 1).

2.2 Data collection

Demographic data such as gender, ethnicity (Chinese, Malay, Asian Indian or others), marital status (never married, currently married, separated/divorced/widowed) and education level (primary—less than 7 schooling years, secondary—between 7-10 years, tertiary - more than 10 years) were collected from self-administered questionnaires. For assessing discriminant validity in the WHOQOL-BREF Physical domain, groups were defined according to the number of co-morbidities (none versus at least one). Co-morbidities, namely retinopathy, cardiovascular, nephropathy, neuropathy, peripheral vascular disease, cerebrovascular disease, anemia, renal and hepatic were obtained from self-reports via questionnaire assessment. The Problem Areas in Diabetes (PAID) was used to assess convergent validity of the WHOQOL-BREF Psychological domain. Participants selfadministered the PAID and Kessler-10 Psychological Distress Scale (K10). For assessing criterion validity, glycemic control (HbA1c), classified either as good (HbA1c \leq 7.0%) or poor (HbA1c > 7.0%) [16], was used. HBA1c levels were collected either a few days before the clinic visit (along with the other blood tests) or on the day itself (as a standalone, finger prick test) at baseline at the National University Hospital. The instrument of interest, WHOQOL-BREF, PAID and K10 are briefly described as follows:

2.2.1 World Health Organization Quality of Life Brief Questionnaire (WHOQOL-BREF)

The WHOQOL-BREF is an abbreviated 26-item version of the WHOQOL-100 consisting of 2 global items and four domains namely: Physical health (7 items), Psychological (6 items), Social relations (3 items) and Environment (8 items). The response format is a 5-point Likert scale with various sets of wordings. The most commonly used scale was: "Very dissatisfied", "Dissatisfied", "Neither satisfied nor dissatisfied", "Satisfied" and "Very satisfied". Item responses are summed within domains to produce a domain score which are then transformed in a scale from 0 to 100 as recommended in the developer's manual [17]. Higher scores indicate better HRQoL. According to the WHOQOL-BREF manual, missing item responses are imputed using the mean of the other items within the domain. Domain scores are calculated if at least 80% of the items had been responded. The only exception is the Social domain, where the domain score should only be calculated if less than 1 item is missing. The WHOQOL-BREF was self-administered by respondents. Our analyses were limited to the WHOQOL-BREF domains (made up of 24 items) because no total or overall scale was available [17] and the 2 global items were generic and not exclusive to WHOQOL-BREF.

2.2.2 Problem Areas in Diabetes (PAID)

The Problem Areas in Diabetes is a self-administered 20-items questionnaire that captures patient's perspective on emotional problems frequently reported in diabetes (type 1 or 2) [18]. Each item in PAID is scored 0 to 4 ("Not a problem" to "Serious Problem"). The sum of the items is multiplied by 1.25 to yield a final score of 0-100 [18]. A high score (\geq 40) indicates presence of severe diabetes related distress [19]. The PAID had been validated globally [20] as well as in a Singapore T2DM population [21].

2.2.3 Kessler-10 Psychological Distress scale (K10)

The Kessler-10 Psychological Distress scale [22] is a generic questionnaire, consisting of 10 items designed to measure the level of distress and severity associated with psychological symptoms in population surveys. Each item in K10 is scored 1 to 5 ("None of the time" to "All of the time"). Item responses are summed to produce an overall score. K10 scores were then categorized into four strata according to standard cut-offs representing low (10 – 15), moderate (16 – 21), high (22 – 30) and very high (31 – 50) psychological distress [23]. The K10 is popular worldwide because the instrument is short, simple to administer, had been validated globally [24] and is used as part of the world mental health survey.

2.3 Statistical analysis

Classical Test Theory methods were used to evaluate the psychometric properties of the WHOQOL-BREF, in the manner recommended by Hobart and Cano [25]. The psychometric properties are data quality, scaling assumptions, internal consistency reliability, targeting and construct (structural, convergent and discriminant) validity and criterion validity. These are briefly described below.

2.3.1 Data quality

This measures the extent to which a scale is administered successfully in a target sample. Indicators of data quality are the percentage of missing item responses and the percentage of the sample for which domain scores can be obtained. The fewer the percentage of

missing item responses and/or the higher the percentage in the sample for whom domain scores can be obtained, the better the data quality.

2.3.2 Scaling assumptions

Since item responses are summed to generate WHOQOL-BREF domain scores, scaling assumptions were verified. These assumptions are 1) items are roughly parallel, i.e. items measure at the same point in the scale and contribute equally to the variance of the domain score, and thus need not be standardized before summation. Items are considered roughly parallel if item means and standard deviations are roughly similar; 2) items within a domain measure the same underlying construct so it is appropriate to combine these to generate a domain score. This criterion is considered met if the smallest corrected item-total correlation is above 0.40 [26]; 3) items within a domain contain a similar proportion of information concerning the construct being measured. This is deemed satisfied if the smallest corrected item-total correct

2.3.3 Reliability

Reliability is the extent to which domain scores are associated with random error: lesser random error more likely indicates that the instrument will produce consistent results across observations. Internal consistency reliability refers to the degree of interrelatedness among items within a scale. Cronbach's alpha coefficient was used to determine internal consistency of the domains. Acceptable internal consistency was defined as Cronbach's alpha ≥ 0.7 [28].

2.3.4 Targeting

Targeting concerns the match between the distribution of disability (say in the physical aspects) due to T2DM in the sample and the distribution of disabilities measured by the WHOQOL-BREF (Physical domain). A better match, determined by examining the skewness of domain score distributions and the presence of floor and ceiling effects suggests higher chances of having a precise measurement. A floor (ceiling) effect was considered present if the percentage of respondents scoring the minimum (maximum) possible score of 0 (100) was >15% [29] or 20% [30].

2.3.5 Construct Validity

Construct validity assesses the degree to which an instrument measures what it was designed to measure and has at least three aspects: structural, convergent/divergent and discriminant [31].

2.3.5.1 Structural construct validity

Principal Component Analyses (PCA with varimax rotation) and Confirmatory Factor Analyses (CFA) were used to ascertain unidimensionality at the domain level. CFA was also done at the overall scale level (excluding the 2 global items) to test the fit of the original 4-factor structure model to the data. In the factor analyses, weighted least squares means and variance adjusted estimation (WLSMV) was employed and (oblique) rotation by the geomin method. Although there are no gold standard rules-of-thumb for deciding unidimensionality, researchers generally seek, for PCA, 1) only one eigenvalue is equal to or greater than 1 [32]; 2) the variance explained by the first principal component is at least 40% [33] and 3) the

ratio of the highest eigenvalue to the second highest eigenvalue is at least 3 to 1 [34,35]. For CFA, conventional model fit criteria are 1) Tucker-Lewis Index (TLI) \ge 0.95 or Comparative Fit Index (CFI) \ge 0.95 combined with Standardized Root Mean Residual < 0.05 or 2) Root Mean Square Error of Approximation (RMSEA) < 0.05 combined with SRMR <0.06, as suggested by Hu and Bentler [36-39]. If the CFA showed lack of fit, exploratory factor analyses (EFA) were carried out to investigate the dimensionality and latent constructs suggested by the data. Dimensionality or the number of factors was decided by considering the following: 1) number of eigenvalues > 1 and scree plot, 2) the quality of factor loadings that is, proximity to simple structure as defined by McDonald [40], which includes considerations of item cross-loading (an item loading > 0.30 in at least two factors) and 3) factor interpretability (each factor has at least three dominant items with loadings > 0.3) and whether the items that load together unto a factor can be meaningfully interpreted [41]. In addition, model fit criteria used in the CFA were also examined to assess the adequacy of the solution.

2.3.5.2 Convergent validity

Pearson's product-moment correlation (rho) between the Psychological domain score with the PAID overall score was used to evaluate convergent validity. A negative and moderately strong correlation was hypothesized that is, H0: rho > -0.30 versus H1: rho \leq -0.30. The hypothesized direction is negative because higher scores are associated with better HRQoL in the WHOQOL-BREF but with greater distress in PAID. The (absolute) cut-off of 0.30 as boundary for a moderate relationship is due to Cohen [42].

2.3.5.3 Discriminant validity

The WHOQOL-BREF Physical domain was examined for discriminant validity. It was hypothesized that the mean Physical score in those with co-morbidities (mean1) would be significantly lower than those without co-morbidities (mean0) [43]. An independent sample t-test was performed to test: H0: mean0 - mean1 \leq 2.5 versus H1: mean0 - mean1 > 2.5 where the threshold of 2.5 is based on the average standard deviation (SD) of the Physical domain scores in those Asian countries (Malaysia, India and Japan) which were sampled in the development of the WHOQOL-BREF [11].

2.3.6 Criterion Validity

The area under the receiver operating curve (AUC) was calculated to determine the ability of the WHOQOL-BREF domains to discriminate between respondents with good and poor diabetes control as reflected by HbA1c. Glycemic control was chosen to assess criterion validity as Testa et al showed that differences in glycemic control clearly affected HRQoL [44]. It was hypothesized that WHOQL-BREF domains were statistically significantly better than chance in discriminating between these health states that is H0: AUC < 0.60 versus H1: AUC > 0.60. In this study, the clinical utility of the WHOQOL-BREF Physical domain was explored by examining its ability to detect those having poor glycemic control. The hypothesized cut-off of 0.60 reflects the trade-off between our ambivalence as regards to the ability of a generic HRQoL to correlate with a clinical marker on one hand and the prospects of utility of the WHOQOL-BREF in clinical settings.

Factor Analyses were performed in Mplus 6.0 [45]. All other analyses were performed in Stata version 12 [46]. The roctab Stata code was used for testing significance on the AUC. All statistical tests were conducted at the 5% level of significance.

3. RESULTS AND DISCUSSION

3.1 RESULTS

A total of 212 subjects were included in the analyses after excluding those with missing data in the WHOQOL-BREF questionnaire (Fig. 1). Table 1 provides the breakdown of the characteristics of our sampled population. The mean (SD) age of the population was 45.8 (11.9) years with 63% males. 50% of the subjects were Chinese, followed by Indians (28%), Malays (11%) and others (10%). A majority of the subjects had more than 10 years of education (58%) and were married (66%). 72% of the subjects had at least one co-morbidity, with retinopathy being the most common co-morbidity (14%), followed by cardiovascular (13%) and nephropathy (8%), to name a few. Almost 70% of the subjects had poor control of their HbA1c. The mean (SD) psychological distress scores, as measured by K10 and PAID, were 23.5 (17.6) and 28.8 (21.8) respectively.



Fig. 1. Schematic representation of the study recruitment of patients with T2DM

3.1.1 Data quality

After imputing 32 data points, there were at most 3 missing data points for each item (Table 2), resulting in a total of 5 subjects (2%) discarded. These findings suggest good data quality.

3.1.2 Scaling assumptions

Table 2 shows the item mean scores, item standard deviations, distribution of responses to each item given as a percentage of the total sample and corrected item–total correlations. Across all domains, the ranges in item mean scores (within each domain) were generally in line with the differences in response distributions: Physical domain items ranging from 3.34

to 4.03, Psychology ranging from 3.50 to 3.79, Social ranging from 3.53 to 3.83 and Environment items means ranging from 3.13 to 3.97. All item variances for each domain were similar, ranging from 0.05 to 0.07. All items, except "How much do you need medical treatment to function in your daily life?" (Item 4) had item-total correlations values that exceeded the requirements of 0.30.

3.1.3 Reliability

Table 2 also shows that Cronbach's alpha of the WHOQOL-BREF domains were in the acceptable range (0.76 to 0.87), indicating good internal consistency.

	All subjects (n=212)							
	n	%	Mean (SD)	95% CI				
Age, in years			45.8 (11.9)	44.2 - 47.5				
Gender								
Male	134	63.2						
Female	78	36.8						
Ethnicity								
Chinese	106	50.0						
Malay	24	11.3						
Indian	60	28.3						
Others	22	10.4						
Education								
< 7 yrs	16	8.1						
7-10 yrs	68	34.3						
> 10 yrs	114	57.6						
Marital status								
Single	40	18.9						
Married	135	65.7						
Divorced/Widowed	22	10.4						
Co-morbidities (yes)								
Retinopathy	28	13.2						
Cardiovascular Disease	28	13.2						
Nephropathy	17	8.0						
Neuropathy	14	6.6						
Cerebrovascular Disease	12	5.7						
Anemia	13	6.1						
PVD	6	2.8						
Hepatic	5	2.4						
Renal	1	0.5						
Glycemic Control								
Good (HbA1c<=7.0)	64	30.2						
Poor (HbA1c>7.0)	148	69.8						
Kessler-10 Psychological Distress scale (K10)			23.5 (17.6)	21.1 - 25.9				
Problem Areas in Diabetes (PAID)			28.8 (21.8)	25.8 - 31.8				

Table 1. Demographic characteristics of sampled population of patients with T2DM

		Item le	vel									Domaiı	n level							
						Perce	ntage an	swered											inter-ite correla	em tion
ltem		No. Miss ^a	No. impute ^b	Mean	SD	1	2	3	4	5	ltem-total corr ^c	Mean	SD⁴	Min ^e	Max ^f	Floor Effect	Ceiling Effect	α_{a}	mean	range
Phys	cal																			
3	To what extent you feel that physical pain prevents you from doing what you need to do?	3	1	3.65	1.04	0.94	14.15	29.72	28.77	25.94	0.46	67.28	14.78	21.42	100	0	0.47	0.8	0.38	(0.24 - 0.77)
4	How much do you need medical treatment to function in your daily life?	3	1	3.34	0.94	1.89	14.15	45.28	25.47	12.74	0.25	_								
10	Do you have enough energy for everyday life?	3	-	3.65	0.77	0.47	6.13	32.55	50	10.85	0.6	_								
15	How well are you able to get around?	2	-	4.03	0.81	0.94	2.36	18.4	49.53	28.77	0.55	_								
16	How satisfied are you with your sleep?	2	-	3.47	0.94	3.3	11.79	28.77	46.7	9.43	0.48	_								
17	How satisfied are you with your ability to perform your daily living activities?	2	1	3.88	0.75	1.42	2.83	17.45	62.26	15.57	0.71	_								
18	How satisfied are you with your capacity to work?	2	-	3.83	0.86	2.36	5.19	17.45	57.55	17.45	0.64	_								

Table 2. Data quality and Scaling assumptions of the items and domains in WHOQOL-BREF

Psvc	nological																			
5	How much do you enjoy life?	3	-	3.55	0.79	1.42	8.02	31.13	52.83	6.6	0.64	66.01	14.37	12.5	100	0	2.36	0.81	0.44	(0.32 - 0.74)
6	To what extent do you feel your life to be meaningful?	3	-	3.68	0.76	0.47	5.19	31.6	51.42	11.32	0.61									,
7	How well are you able to concentrate?	3	-	3.64	0.68	-	3.77	36.32	51.89	8.02	0.55									
11	Are you able to accept you bodily appearance?	3	3	3.50	0.96	3.77	10.38	29.72	43.4	11.79	0.57									
19	How satisfied are you with yourself?	3	-	3.79	0.81	1.42	4.72	22.64	56.13	15.09	0.63									
26	How often do you have negative feelings such as blue mood, despair, anxiety, depression? (reversed)	3	2	3.69	0.78	1.42	6.13	23.58	58.96	8.96	0.46									
Socia 20	How satisfied with your personal relationships?	3	-	3.83	0.83	1.89	3.3	22.64	54.25	17.92	0.59	67.73	17.59	0	100	0.47	8.02	0.76	0.52	(0.50 - 0.56)
21	How satisfied are you with your sex life?	3	14	3.53	0.89	3.77	5.19	34.91	42.92	10.38	0.86									
22	How satisfied are you with the support you get from your friends?	3	-	3.76	0.85	1.89	4.72	25	51.89	16.51	0.84									
Envir	onment	0	0	2.00	0.70	0.47	F 40	20.55	50.0	7	0.50	05.40	45 47	45.00	100	0	4 40	0.07	0.40	(0.00
8	How sate do you feel in your	3	2	3.62	0.72	0.47	5.19	32.55	53.3	1.55	0.59	65.19	15.17	15.63	100	U	1.42	0.87	0.46	(0.29 - 0.67)

	everyday life?										
9	How healthy is your physical environment?	3	3	3.47	0.83	2.83	6.6	36.79	45.75	6.6	0.62
12	Have you enough money to meet your needs?	3	-	3.41	1.00	4.72	11.32	34.43	37.74	11.79	0.74
13	How available to you is the information you need in your day-to-day life?	3	1	3.58	0.79	1.89	5.19	34.43	50.47	8.02	0.68
14	To what extend do you have the opportunity for leisure activities?	3	-	3.13	0.93	4.72	17.45	43.4	28.77	5.66	0.58
23	How satisfied are you with the conditions of your living place?	3	-	3.97	0.77	1.42	3.3	12.74	61.79	20.75	0.54
24	How satisfied are you with your access to health services?	3	2	3.87	0.72	0.94	2.36	20.28	60.38	15.09	0.66
25	How satisfied are you with your transport?	3	2	3.81	0.90	3.77	5.19	13.21	60.38	16.51	0.59

^a No. Missing: Number of missing responses to the items, ^b No. Impute: Number of missing responses with imputed values, ^c Item-total correlation, ^d Standard deviation, ^e Minimum value, ¹ Maximum value, ^g Cronbach's alpha

3.1.4 Targeting

Fig. 2 shows the distribution of WHOQOL-BREF domain scores. The percentage of people responding across the different items covers the complete scale range of 0 to 100. None of the domains exhibited floor or ceiling effects according to the pre-specified cut-offs, 15% and 20% respectively. In addition, we noticed that all domain scores were mildly skewed to the left.



Fig. 2. Distribution of WHOQOL-BREF domain scores –Physical, Psychological, Social and Environment

3.1.5 Construct Validity

3.1.5.1 Structural validity

Table 3 provides results for the CFAs and the PCAs. Domain level PCAs showed that all domains were unidimensional, except the Physical domain which had two eigenvalues > 1.0. CFA for each WHOQOL-BREF domains showed that three of four domains (Physical, Psychological and Environment) did not have good fit statistics, suggesting that the domains were not unidimensional. CFA on the 24 items (excluding two global items) rejected the plausibility of the original 4-factor structure.

Dom	nains/Items	CFA	PCA			
		Item factor Ioadings	Rotatec matrix wl set as eig	l component hen extraction envalues > 1.0		
			1	2		
Phy	sical					
3	To what extent you feel that physical pain prevents you from doing what you need to do?	0.51	0.36	0.69		
4	How much do you need medical treatment to function in your daily life?	0.26	0.001	0.89		
10	Do you have enough energy for everyday life?	0.70	0.69	0.26		
15	How well are you able to get around?	0.74	0.73	0.20		
16	How satisfied are you with your sleep?	0.65	0.70	0.04		
17	How satisfied are you with your ability to perform your daily living activities?	0.99	0.91	0.10		
18	How satisfied are you with your capacity to work?	0.87	0.84	0.08		
Fit s	tatistics		· · · · · · · · · · · · · · · · · · ·			
	Chi-square (> 0.05)	< 0.0001				
	CFI (> 0.95)	0.98				
	TLI (> 0.95)	0.96				
	RMSEA (< 0.06)	0.15				
	WRMR (< 2)	0.91				
	Variance explained, R2		0.49			
	Ratio of eigenvalues		3.07			
Psy	chological					
5	How much do you enjoy life?	0.91	0.81			
6	To what extent do you feel your life to be meaningful?	0.85	0.78			
7	How well are you able to concentrate?	0.65	0.69			
11	Are you able to accept you bodily appearance?	0.70	0.72			
19	How satisfied are you with yourself?	0.73	0.75			
26	How often do you have negative	0.51	0.56			
	feelings such as blue mood, despair,					
	anxiety, depression? (reversed)					
Fit s	tatistics					
	Chi-square (> 0.05)	< 0.0001				
	CFI (> 0.95)	0.94				
	TLI (> 0.95)	0.90				
	RMSEA (< 0.06)	0.22				
	WRMR (< 2)	1.26				
	Variance explained, R2		0.52			
	Ratio of eigenvalues		3.81			
Soc	ial					
20	How satisfied with your personal relationships?	0.82	0.84			
21	How satisfied are you with your sex life?	0.81	0.84			
22	How satisfied are you with the support	0.70	0.78			

Table 3. Confirmatory Factor Analyses (CFA) and Principal Component Analyses(PCA) of the WHOQOL-BREF

	you get from your friends?		
Fit s	statistics		
	Chi-square (> 0.05)	< 0.0001	
	CFI (> 0.95)	1.00	
	TLI (> 0.95)	1.00	
	RMSEA (< 0.06)	< 0.0001	
	WRMR (< 2)	< 0.0001	
	Variance explained, R2		0.680
	Ratio of eigenvalues		3.66
Env	ironment		
8	How safe do you feel in your everyday life?	0.75	0.69
9	How healthy is your physical environment?	0.76	0.74
12	Have you enough money to meet your needs?	0.83	0.81
13	How available to you is the information you need in your day-to- day life?	0.79	0.77
14	To what extend do you have the opportunity for leisure activities?	0.62	0.65
23	How satisfied are you with the conditions of your living place?	0.67	0.66
24	How satisfied are you with your access to health services?	0.82	0.76
25	How satisfied are you with your transport?	0.77	0.73
Fit s	tatistics		
	Chi-square (> 0.05)	< 0.0001	
	CFI (> 0.95)	0.96	
	TLI (> 0.95)	0.94	
	RMSEA (< 0.06)	0.15	
	WRMR (< 2)	1.11	
	Variance explained, R2		0.53
	Ratio of eigenvalues		4.76

These results indicating lack of fit prompted an EFA to suggest alternative factor structures for this sample of patients with T2DM in Singapore. In the EFAs, we explored various solutions for the best model fit by limiting the number of factors to be extracted from 1 to 7. Based on the dimensionality and fit criteria, a 4-factor model was deemed most reasonable (Appendix A). When the items from the Singapore 4-factor model were compared with the original WHOQOL-BREF (Table 4), contents of 2 of the factors were largely similar to the original WHOQOL-BREF Physical and Environment domains, respectively. However, the third factor is a combination of items from the Psychological and Social domains while the fourth factor is a combination of items from the Physical and Environment domains.

Origi	nal factor structure	Sin	gapore's factor structure
Phys	ical	Fac	tor 1
3	To what extent you feel that physical pain prevents you from doing what you need to do? How much do you need medical treatment to function in your daily life?	3	To what extent you feel that physical pain prevents you from doing what you need to do?
10 15 16 17 18	Do you have enough energy for everyday life? How well are you able to get around? How satisfied are you with your sleep? How satisfied are you with your ability to perform your daily living activities? How satisfied are you with your capacity to work?	10 15 16 17 18 19 20 21 23	Do you have enough energy for everyday life? How well are you able to get around? How satisfied are you with your sleep? How satisfied are you with your ability to perform your daily living activities? How satisfied are you with your capacity to work? How satisfied are you with yourself? How satisfied with your personal relationships? How satisfied are you with your sex life? How satisfied are you with your access to health services?
Envi	ronment	Fac	tor 2
8 9	How safe do you feel in your everyday life? How healthy is your physical environment?	11	Are you able to accent you bodily appearance?
12	Have you enough money to meet your needs?	12	Have you enough money to meet your needs?
13	How available to you is the information you need in your day-to-day life?	13	How available to you is the information you need in your day-to-day life?
14	To what extend do you have the opportunity for leisure activities?	14	To what extend do you have the opportunity for leisure activities?
23	How satisfied are you with the conditions of your living place?		
24	How satisfied are you with your access to health services?	24	How satisfied are you with your access to health services?
25	How satisfied are you with your transport?	25	How satisfied are you with your transport?
Psychological			tor 3
5	How much do you enjoy life?	5	How much do you enjoy life?

Table 4. Comparison between the original WHOQOL-BREF factor structure and the Singapore factor structure

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6 7 11 19	To what extent do you feel your life to be meaningful? How well are you able to concentrate? Are you able to accept you bodily appearance? How satisfied are you with yourself?	6	To what extent do you feel your life to be meaningful?
	· · · · · · · · · · · · · · · · · · ·	22	How satisfied are you with the support you get from your friends?
26	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	26	How often do you have negative feelings such as blue mood, despair, anxiety, depression?
Soci	al		
20	How satisfied with your personal relationships?		
21	How satisfied are you with your sex life?		
22	How satisfied are you with the support you get from your friends?		
		Fac	ctor 4
		7	How well are you able to concentrate?
		8	How safe do you feel in you everyday life?
		9	How healthy is your physical environment?

3.1.5.2 Convergent validity

Correlation between the WHOQOL-BREF Psychological domain scores and the PAID overall score was negatively correlated (r=-0.38) and statistically significant (p<0.0001), suggesting that the Psychological domain was measuring a similar concept as the PAID.

3.1.5.3 Discriminant validity

The independent t-test to compare Physical domain scores between patients with and without comorbidities showed a mean difference of 3.04 (p=0.03), which was statistically significant indicating sufficient evidence to support discriminant validity.

3.1.6 Criterion Validity

The AUCs across all WHOQOL-BREF domains were in the range of 0.4 when discriminating those with good versus poor control of HbA1c (Table 5). Similarly, the WHOQOL-BREF Physical domain had an AUC of 0.45 when discriminating those with and without comorbidities. This suggests that the WHOQOL-BREF domains were poor at discriminating between the various patient groups.

Table 5. Criterion validity of the WHOQOL-BREF domain scores

	Physical	Psychological	Social	Environment
Correlation with HbA1c	-0.21	-0.20	-0.20	-0.27
Significance	0.0019	0.0029	0.0031	0.0001
AŬC	0.40	0.45	0.44	0.41

3.2 DISCUSSION

In this study to evaluate the psychometric properties of the WHOQOL-BREF among patients with T2DM, we have found the WHOQOL-BREF domains exhibited good data quality, met the scaling assumptions, had satisfactory targeting and achieved internal consistency. However, construct validity (in terms of structural validity) and criterion validity with respect to HbA1c posed some concerns and would require further evaluation.

While generic HRQoL questionnaires may be expected to be less sensitive and responsive than disease-specific HRQoL questionnaires, they should still meet basic criterion or discriminant validity. When we separately looked at how the K10 and the WHOQOL-BREF Psychological domain performed in patients with good and poor glycemic control (results not shown), only the K10 instrument had statistically significant score difference (mean difference=8.05, p=0.0023) between the two groups of patients, which was in line with previous studies [47,48]. This may pose concerns to the validity of the WHOQOL-BREF Psychological domain in studies involving patients with T2DM.

The CFA did not support the factor structure of the WHOQOL-BREF as suggested by the developer. The PCA also did not support unidimensionality of the WHOQOL-BREF Physical domain, although the Psychological, Social and Environment domains were consistent with unidimensionality. In the EFA, among the solutions explored, the 4-factor model was deemed the best according to dimensionality (Appendix B) and model fit criteria. When this 4-factor model was compared to the original WHOQOL-BREF factor structure, not all the domains

could be assigned meaningful names based on the contents. This means that the concepts being measured were not equivalent with the original questionnaire.

On one hand, the limitations of WHOQOL-BREF may be due to the instrument per se. In previous Singapore studies which used the WHOQOL-BREF, we had mixed findings in terms of the ability of the WHOQOL-BREF domains to discriminate various health states of patients [12-14]. In one population of patients with schizophrenia, we observed that the WHOQOL-BREF domains were able to discriminate between those with comorbid depression versus those with none [13]. However, in another population of patients with schizophrenia, only the Physical domain of the WHOQOL-BREF was able to effectively discriminate between patients with and without physical comorbidity [12]. Taiwan, to the best of our knowledge, was the only other country in Asia that had used the WHOQOL-BREF extensively [49-51]. We noticed that that in all 3 studies in Taiwan, several WHOQOL-BREF domains were unable to discriminate between the various comparison groups, except for the Physical domain. The lack of sensitivity of the WHOQOL-BREF domains (apart from the Physical domain) in the abovementioned studies suggest that the questionnaire might not be sufficiently sensitive in discriminating those with menopausal symptoms, pulmonary tuberculosis and among mothers of children with asthma. On the other hand, the limitations may be due to the population under study (i.e. T2DM). We identified a total of 11 that used the WHOQOL-BREF among patients with T2DM. Of the 11 studies, 3 were conducted in Asia (China, Taiwan and Thailand) [52-54]. In the Taiwan study, the WHOQOL-BREF Taiwan version (with 28 items, including 2 general items, 24 domain-specific WHOQOL-BREF items and 2 additional national items specific for the culture of the Taiwanese) was used. In the Thailand and China study, the Thai and Chinese language version of the WHOQOL-BREF was used respectively. In all 3 studies, only the internal consistency of the domains was reported and there were no mentions about the validity of the instrument within the study. To the best of our knowledge, this is the first study of the psychometric performance of the original WHOQOL-BREF in Asian T2DM.

We recognize that this study has several limitations. First, the use of HbA1c, a laboratory marker, to assess criterion validity of HRQoL questionnaire may be criticized as inappropriate. Nonetheless, it is acknowledged that in evaluating HRQoL, no true gold standard exists [55] and therefore the use of HbA1c as a criterion may be described as pragmatic at best. Furthermore, studies have found that good metabolic control were associated with better HRQoL [44,56]. Second, our sampled population was based on a convenience sample. Classical Test Theory methods are reliant on having a random sample [57]. Furthermore, our sample was drawn from a specialist out-patient clinic of the National University Hospital. Hence, the findings might be limited to the sampled population. Third, the study did not include the qualitative evaluation of the WHOQOL-BREF which would have allowed us to assess the relevance and representativeness [58] of the questionnaire among patients with T2DM. Fourth, the comorbidities were self-reported, instead of being extracted from case notes. However, studies had reported high levels of agreement between selfreport and medical record for patients with diabetes [59]. Last, we only captured Englishspeaking patients, thus limiting the generalizability of our findings. However, based on the Singapore Census 2010, 75% of the Singapore resident population aged 25 to 65 was English-literate [60].

4. CONCLUSION

The WHOQOL-BREF domains exhibited good data quality, met the scaling assumptions, had no floor or ceiling effects and achieved good reliability (discriminant validity in the Physical

domain was attained and the Psychological domain demonstrated convergent validity with PAID) among patients with T2DM in Singapore. However, problems with the construct validity mean that it is not clear what concepts of HRQoL are being measured by WHOQOL-BREF domains. The failure of the WHOQOL-BREF domains to discriminate patients based on HbA1c suggests its limited application as an evaluative instrument. However, its utility as a predictive instrument remains to be determined in future studies. Thus, we recommend that an adequately powered random sample of T2DM patients in Singapore be studied to confirm the findings of our study.

CONSENT

All authors declare that 'written informed consent was obtained from the patient (or other approved parties) for publication of this case report and accompanying images.

ETHICAL APPROVAL

The authors have obtained all necessary ethical approval from the National Healthcare Group Domain Specific Review Board.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX

Appendix A. Factor Loadings^a from Exploratory Factor Analyses

	Items	Factor 1	Factor 2	Factor 3	Factor 4
3	To what extent you feel that physical pain prevents you from doing what you need to do?	0.3687	0.1578	0.0827	0.1602
4	How much do you need medical treatment to function in your daily life?	0.1034	0.0891	-0.0155	0.1694
5	How much do you enjoy life?	0.2509	0.1216	0.7254	0.2837
6	To what extent do you feel your life to be meaningful?	0.1057	0.1712	0.8004	0.2053
7	How well are you able to concentrate?	0.1937	0.1892	0.2622	0.6754
8	How safe do you feel in your everyday life?	0.2472	0.2962	0.262	0.6802
9	How healthy is your physical environment?	0.2746	0.3763	0.3955	0.4137
10	Do you have enough energy for everyday life?	0.4614	0.3726	0.2537	0.3751
11	Are you able to accept you bodily appearance?	0.3373	0.3612	0.3258	0.312
12	Have you enough money to meet your needs?	0.2063	0.7112	0.1802	0.2631
13	How available to you is the information you need in your day-to-day life?	0.0955	0.6807	0.0987	0.3697
14	To what extend do you have the opportunity for leisure activities?	0.3355	0.3634	0.2149	0.2128
15	How well are you able to get around?	0.5305	0.4429	0.1857	0.1887
16	How satisfied are you with your sleep?	0.5828	0.1367	0.2251	-0.009
17	How satisfied are you with your ability to perform your daily living activities?	0.8866	0.1434	0.1481	0.1215
18	How satisfied are you with your capacity to work?	0.7856	0.1765	0.0472	0.2709
19	How satisfied are you with yourself?	0.6603	0.2369	0.3723	0.1767
20	How satisfied with your personal relationships?	0.4941	0.2515	0.351	0.096
21	How satisfied are you with your sex life?	0.3945	0.3127	0.3941	0.1923
22	How satisfied are you with the support you get from your friends?	0.2878	0.4124	0.4851	0.041
23	How satisfied are you with the conditions of your living place?	0.4889	0.3854	0.4655	-0.0844
24	How satisfied are you with your access to health services?	0.382	0.5791	0.2753	0.152
25	How satisfied are you with your transport?	0.3285	0.6292	0.1961	0.0311
26	How often do you have negative feelings such as blue mood, despair, anxiety,	0.2811	0.0347	0.3205	0.2094

such as blue moou, despen, and a such as blue moou, despen, and a such as blue moou, despen, and a such as the suc



Appendix B. Scree plot from Exploratory Factor Analyses suggesting the number of factors for the WHOQOL-BREF

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