

1 **002Validity and Reliability of the 19-item Audit of Diabetes-Dependent Quality of Life**
2 **(ADDQoL-19) Questionnaire in Chinese Patients with Type 2 Diabetes Mellitus in**
3 **Primary Care**

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Abstract

Background: This study aimed to determine the psychometric properties of the 19-item ADDQoL (ADDQoL-19) in Chinese patients with Type 2 diabetes mellitus (T2DM) in primary care setting.

Methods: The ADDQoL-19 and SF-12v2 were administered to 386 Chinese patients with T2DM in public primary outpatient clinic in Hong Kong. Internal consistency reliability was determined by Cronbach's alpha whereas construct validity was assessed by the Spearman's correlations between the scores of the ADDQoL-19 and SF-12v2. Independent t-tests were used in known-groups comparisons to identify the differences in the ADDQoL-19 scores between respondents with different duration of diabetes, treatment modalities, body mass index and glycemic control.

Results: The ADDQoL-19 had a moderate to weak correlation with SF-12v2 in convergent validity but with statistically significant results in known-groups comparisons. Good internal consistency was generated with an acceptable value of 0.81, which was comparable to original English version. Construct validity was proven except the convergent validity is found to be weak with the generic SF-12v2, which was similar to the results in prior psychometric studies.

Conclusions: Despite weak convergent validity, the ADDQoL-19 was found to have a satisfactory psychometric property especially known-groups comparisons and internal consistency reliability in the primary care setting.

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Keywords: Quality of life; Validity; Type 2 Diabetes; Chinese; Primary care; ADDQoL-19

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48 Introduction

49 Diabetes mellitus (DM) has become one of the most prevalent chronic diseases
50 in the world with an estimated number of people with DM to be over 592 million by year
51 2035 [1]. Patients with DM are at high risk of serious complications, including neuropathy to
52 cardiovascular diseases [2]. Apart from the physical disability, the psychosocial burdens
53 carried by DM patients also affect their quality of life and daily self-care capability.
54 Assessing health-related quality of life (HRQOL) in patients is important as it involves
55 patient-oriented measurement of treatment outcomes instead of just physical assessments [3-
56 6]. Generic and condition-specific instruments are the two main categories in assessing the
57 HRQOL of patients with DM. The 19-item Audit of Diabetes-Dependent Quality of Life
58 (ADDQoL-19) aims to measure diabetes-specific HRQOL of patients with type 1 or type 2
59 DM with a weighting system for indicating the perceived impact and the importance of the
60 measured aspects of life [7-9]. Since diabetes is a prevalent disease that may impair patients'
61 quality of life in various way, having a diabetic-specific instrument would be a more effective
62 and accurate tool to reflect and compare the quality of life within DM patients. This research
63 is the first study to test the validity and reliability of the traditional Chinese version of
64 ADDQoL-19 in patients with DM in primary care setting. Prior studies were only conducted
65 with the simplified Chinese version of the ADDQoL-19 in China and Singapore but is only
66 limited to the hospital-care setting [10; 11]. Given the chronicity nature of diabetes mellitus
67 and most of the diabetic patients are asymptomatic most of the time in their disease course,
68 majority of patients with the diagnosis of DM live in the community and receive continuous
69 and comprehensive health care from out-patient clinics in the community at the primary care
70 level settings, instead of secondary or tertiary health care which are provided in the hospital

71 settings. For example, in Hong Kong, there are around 173,015 diabetic patients receiving
72 continuous care under the public primary care settings in 2013[12]. Therefore, testing the
73 validity and reliability of the ADDQoL-19 in a primary care environment could provide a
74 more comprehensive picture of its accuracy and applicability to patients with DM under the
75 community care. The aim of this study was to determine the validity and reliability of
76 traditional Chinese version of the ADDQoL-19 to assess the QOL of Chinese patients with
77 type 2 DM under the primary care.

78 **Method**

79 *Subject and Study Design*

80 A cross-sectional study on 386 recruited Chinese patients with type 2 DM under the
81 care of a public general out-patient clinic from August 2011 to November 2011 was
82 conducted. Convenience sampling on eligible patients aged 18 or above was performed.
83 Institutional ethics approval was obtained before the start of our study and written consent
84 from subjects were obtained prior to data collection. Invited participants who had signed their
85 consented were then asked to complete a structured questionnaire that included Chinese Short
86 Form 12-item Health Survey (SF-12v2), 19-item ADDQoL and socio-demographic questions.
87 Clinical characteristics (duration of DM, treatment modalities, body mass index,
88 Haemoglobin A1c) of patients were extracted from patients' medical records in the Hospital
89 Authority clinical management system.

90 *Study Instruments*

91 *The 19-item Audit of Diabetes-Dependent Quality of Life (ADDQoL-19)*

92 The ADDQoL-19 is a condition-specific HRQOL instrument assessing the impact and
93 importance of DM on various aspects of quality of life (QOL) to diabetic patients. Three key

94 scores, “Present QOL score”, “Diabetes-dependent QOL (the quality of life would-be if they
95 did not have diabetes) score”, and “Average weighted impact score” are used to reflect the
96 impact of DM on one’s quality of life. “Present QOL score” is concerned about the patient’s
97 current quality of life. “Diabetes-dependent QOL score” measures how quality of life of
98 patients would be if they did not have diabetes and is dependent on the diabetes conditions.
99 These two overview items are measured on a 7-point scale where +3 represents excellent and
100 -3 represents extremely bad (e.g. from -3 to +3). Following these two items are the 19
101 diabetes –specific domain items which are used for assessing a particular aspect of the QOL
102 if diabetes was absent. All the 19 questions are measured on a 5-point scale, ranging from -3
103 (greatest negative impact) to +1 (greatest positive impact). Subjects are also required to give
104 an “importance score” rating for these 19 domains on a 5-point scale, from 0 (not at all
105 important) to 3 (very important). The option of “non-applicable” is included in five of the
106 domains (working life, holidays, family life, closest personal relationship and sex life) if it is
107 considered to be irrelevant by the subjects. The weighted impact (WD) score is calculated by
108 multiplying the importance scores and impact scores. The average weighted impact (AWI)
109 score is obtained by averaging all the weighted scores and is interpreted as the overall
110 weighted impact score of DM on quality of life.

111 *Short Form 12-item Health Survey (SF-12v2)*

112 The SF-12v2 is a widely-used generic HRQOL instrument that covers eight HRQOL
113 domains and each domain score ranges from 0 to 100, with higher score implies better
114 HRQOL. The traditional Chinese version of SF-12v2 was validated [13; 14] with acceptable
115 psychometric properties and normed in Chinese general population before [15], thus it was
116 used to measure generic HRQOL in the same population with DM[16; 17].

117 *Data Analysis*

118 Descriptive statistics was computed to summarize the socio-demographic and clinical
119 characteristics. Internal consistency reliability was determined by Cronbach's alpha where
120 the coefficient above 0.7 was considered acceptable reliability[18]. Convergent validity was
121 assessed by the Spearman's correlations between the ADDQoL-19 and SF-12v2. Spearman's
122 correlation can be used in the variables not normally distributed and provide more robust to
123 outliers than Pearson's correlation[19]. Correlations coefficients were interpreted as, weak for
124 coefficient of <0.3, moderate for coefficient of 0.3-0.5, strong for coefficient of 0.5-0.69 and
125 very strong for coefficient of 0.70-1.00[20]. Independent t-tests were used in known-groups
126 comparisons between patient's characteristics to identify the differences in the ADDQoL-19
127 scores between respondents with different durations of DM (<10 years and ≥ 10 years),
128 treatment modalities (treated with oral hypoglycemia drug or insulin), Body mass index (BMI)
129 (obese with $BMI \geq 25$ kg/m²) and glycemic control (Glycated haemoglobin A1c <7% as
130 optimal control and $\geq 7\%$ as poor control). The threshold for BMI and Glycated haemoglobin
131 A1c are based on the local guidance from Hong Kong Reference Framework for Diabetes
132 Care for Adults in Primary Care Settings [21]. It was hypothesized that the ADDQoL-19
133 AWI scores were lower in patients with longer duration of DM, without any DM medication
134 treatment, and with obesity as in previous studies [9; 11; 22; 23].

135 Statistical analyses were performed using SPSS Windows 20.0 program (IBM SPSS,
136 Chicago IL, USA).

137 **Results**

138 The result of the ADDQoL-19 is shown in Table 1. Findings revealed that patients
139 with DM had negative impacts on all the life domains in ADDQoL-19. The greatest impact
140 and the least impact life domains before weighting and after weighting were "freedom to eat"

141 and “living condition” respectively. The frequency of using “not applicable” response ranged
142 from 66.2% (“sex life”) to 3.9 % (“family life”).

143 The result of convergent validity is listed in Table 2. Only moderate correlations were
144 found in vitality ($r=0.334$), role limitation due to emotional problems ($r=0.354$), mental
145 health ($r=0.397$) and mental health composite ($r=0.385$) with average weighted impact score of
146 the ADDQoL-19.

147 The sensitivity of the ADDQoL-19 to discriminate across groups is shown in Table 3.
148 The results showed that patients with more than 10 years of DM differed significantly than
149 those who were less than 10 years. Statistically significant difference could also be detected
150 between DM patients with and without obesity. The use of oral hypoglycemic drug and DM
151 medication was differentiated by the ADDQoL-19 statistically, but not for the use of insulin
152 treatment and the clinical group of glycemic control. Lastly, acceptable reliability with
153 Cronbach’s alpha coefficient of 0.81 was found in terms of internal consistency.

154 Discussion

155 The aim of the study was to investigate the psychometric properties of the 19-item
156 ADDQoL-19 by comparing the convergent validity and the known-groups comparisons
157 among DM patients in primary care setting. Reliability in current study was also assessed to
158 investigate in its internal consistency with acceptable value of 0.81, which was comparable to
159 original English version (0.85) [9] and other studies (0.88-0.95) in Malaysia, Australia and
160 United Kingdom [10; 11; 24-29]. Significant results were generated in known-groups
161 comparisons while the convergent validity achieved modest to weak values in some domains.
162 Only mental composite summary score in SF-12v2 could achieve moderate correlation but
163 others were weakly correlated. Such result was consistent in other previous studies which
164 only greater coefficients were found in mental component summary score and there was a

165 weak or moderate correlation between the disease-specific ADDQoL-19 and the generic
166 instruments such as Short Form 36 Health Survey (SF-36), Short Form 6 dimension Health
167 Survey (SF-6D) and general EuroQoL indices (EQ-5D) [10; 11; 24-28]. One of the possible
168 reasons is the overlapping construct was limited between the ADDQoL-19 and the SF-12v2
169 and was only restricted to the mental health area. It shows the restriction of the generic
170 instrument in interpreting the HRQOL of DM patients. However, it should be noted that the
171 correlation values in weighted average score was higher than the unweighted ones, which
172 exemplified the importance of the weighting systems [25-27]. A greater percentage of “non-
173 applicable” responses were found in life domains of sex life, closest personal friendship,
174 working life, holidays and family, which were similar to the results in prior studies [11; 23;
175 24]. The ability to discriminate across clinical groups was statistically significant in the
176 ADDQoL-19. Patients who were on hypoglycemic drug or obese reported to have a higher
177 negative AWI score and was consistent to prior literature that patients with chronic
178 medications had worse HRQOL compared to those on diet and exercise control alone [30; 31].
179 The stress originated from keeping good regimen of medication may hamper the HRQOL.
180 Although the result generally supported that the ADDQoL-19 is feasible to apply on Chinese
181 diabetic patients in primary care system, it should be noted that subjects recruited in this
182 study comes from only one general out-patient clinic. Further investigation should be spread
183 to other specialist outpatient clinics or private doctor clinics with a more diverse sample.
184 Cautions should also be paid on the weak to moderate correlation with the SF-12v2. Future
185 validation should investigate more to confirm the convergent validity or use another generic
186 instrument to validate the ADDQoL-19.

187 **Conclusion**

188 The ADDQoL-19 had a moderate to weak correlation with SF-12v2 in convergent validity
189 but with statistically significant results in known-groups comparisons. Good internal

190 consistency was generated with an acceptable value of 0.81, which was comparable to
191 original English version. Construct validity was proven except the convergent validity is
192 found to be weak with the generic SF-12v2. Nevertheless, the ADDQoL-19 was found to
193 have a satisfactory psychometric property especially known-groups comparisons and internal
194 consistency reliability in the primary care setting.

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198 **List of abbreviations used**

199 DM, Diabetes mellitus; HRQOL, Health-related quality of life; ADDQoL-19, The Audit of
200 Diabetes-Dependent Quality of Life; BMI, Body mass index; QOL, quality of life.

201

202 **Competing interests**

203 The authors declare that they have no competing interests.

204

205 **Authors' contributions**

206 CF and CW provided direct input into the design and execution of the study. CW and YFW
207 undertook statistical analysis and generated the results. CF, CW, CY and YFW drafted the
208 manuscript. All authors contributed to its editing. All authors read and approved the final
209 manuscript.

210

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Table 1. Distribution of the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) Impact, Importance and Weighted Impact Scores

Life Domain	Impact scores (Mean±SD)	Importance scores (Mean±SD)	Weighted impact scores* (Mean±SD)	Rank†	% of zero importance scores	% of NA options
Leisure activities	-0.67±0.65	1.81±0.51	-1.27±1.31	5	3.6	
Working life‡	-0.64±0.76	2.00±0.47	-0.48±1.19	12	1.4	62.7
Local or long-distance journeys	-0.38±0.63	1.52±0.73	-0.55±1.02	11	13.2	
Holidays‡	-0.52±0.66	1.83±0.57	-0.41±1.03	13	2.1	60.9
Physical health	-0.73±0.60	1.90±0.37	-1.43±1.20	4	1.6	
Family life‡	-0.36±0.61	2.03±0.36	-0.73±1.37	8	0.5	3.9
Friendship and social life	-0.18±0.47	1.57±0.62	-0.35±1.07	14	5.2	
Closest personal relationship‡	-0.47±0.73	1.44±0.66	-0.27±0.91	15	2.6	63.6
Sex life‡	-0.51±0.75	1.39±0.59	-0.25±0.82	16	1.6	66.2
Physical appearance	-0.35±0.57	1.46±0.75	-0.65±1.20	9	13.5	
Self-confidence	-0.57±0.65	1.91±0.40	-1.16±1.44	6	1.8	
Motivation	-0.49±0.60	1.84±0.45	-0.97±1.28	7	2.6	
People's reaction	-0.13±0.40	0.66±0.76	-0.22±0.83	17	50.8	
Feelings about the future	-0.77±0.61	1.80±0.54	-1.52±1.32	3	4.9	
Financial situation	-0.31±0.57	1.84±0.57	-0.64±1.23	10	5.7	
Living conditions	-0.03±0.19	1.35±0.58	-0.05±0.42	19	3.4	
Dependence on others	-0.07±0.33	1.72±0.73	-0.12±0.73	18	11.7	
Freedom to eat	-1.79±0.69	1.95±0.55	-3.63±1.99	1	1.6	
Freedom to drink	-1.47±0.74	1.50±0.66	-2.41±1.93	2	3.4	

Note:

* Weighted impact score is calculated as the mean of the product of impact and importance scores.

† 1 being the greatest; items with the same mean weighted impact scores are tied (i.e. have the same rank)

‡ Respondents were able to indicate 'NA' as a response to these five items.

Table 2. Convergent Validity of the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19)

Spearman Correlation	Present QOL score	Diabetes-dependent QOL score	Average Weighted Impact Score
SF-12v2			
PF	0.039	0.050	0.150
RP	0.059	0.065	0.231
BP	0.054	0.217	0.288
GH	0.290	0.109	0.174
VT	0.155	0.190	0.334
SF	0.030	0.141	0.296
RE	0.223	0.180	0.354
MH	0.223	0.105	0.397
PCS	0.078	0.102	0.135
MCS	0.213	0.155	0.385
ADDQoL-19			
Present QOL score	1.000	0.044	0.174
Diabetes-dependent QOL score	0.044	1.000	0.387
Average Weighted Impact Score	0.174	0.387	1.000

Note: PF= physical functioning; RP=role limitations due to physical health problems; BP=bodily pain; GH=general health perceptions; VT=vitality; SF=social functioning; RE=role limitations due to emotional problems; MH= mental health; PCS=physical composite summary; MCS= mental composite summary

Table 3. Known-groups Comparisons of the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19)

Known-group	Present QOL score	Diabetes-dependent QOL score	Average Weighted Impact Score
Duration of DM			
< 10 years	0.50±0.62	-1.04±0.72	-1.08±0.74
≥ 10 years	0.59±0.61	-1.08±0.67	-0.88±0.53
P-value	0.200	0.644	0.020*
Treatment Modalities			
Non-Oral Hypoglycemic Drug Treated	0.60±0.60	-0.89±0.66	-0.89±0.53
Oral Hypoglycemic Drug Treated	0.49±0.62	-1.10±0.71	-1.08±0.74
P-value	0.138	0.013*	0.025*
Non-Insulin Treated	0.51±0.62	-1.05±0.70	-1.03±0.71
Insulin Treated	0.58±0.51	-1.00±0.74	-1.25±0.51
P-value	0.699	0.806	0.279
No DM Medication Treated	0.60±0.60	-0.91±0.66	-0.88±0.53
DM Medication Treated	0.49±0.62	-1.09±0.71	-1.08±0.74
P-value	0.129	0.033*	0.020*
Obesity			
BMI < 25 kg/m ²	0.50±0.60	-1.05±0.70	-0.95±0.65
BMI ≥ 25 kg/m ²	0.53±0.63	-1.05±0.71	-1.10±0.74
P-value	0.594	0.929	0.035*
Glycemic Control			
HbA1c < 7%	0.54±0.63	-1.02±0.69	-1.02±0.74
HbA1c ≥ 7%	0.50±0.61	-1.08±0.71	-1.04±0.67
P-value	0.484	0.403	0.782

Note: BMI=Body mass index; HbA1c=Glycated haemoglobin A1c

* $p < 0.05$