Original

Reliability and Validity of Mongolian Version of Diabetes Quality of Life Brief Clinical Inventory for Type II Diabetes

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Abstract

Background: Diabetes mellitus (DM) is a global health challenge affecting patient well-being and quality of life (QoL). This study aimed to validate the Mongolian version of the Diabetes Quality of Life Brief Clinical Inventory (MVDQOL-BCI) in patients with type II DM in Mongolia.

Methods: Data were collected from 197 participants across three hospitals in Ulaanbaatar. Reliability was assessed using Cronbach's alpha and the intraclass correlation coefficient (ICC). Pearson's correlation was used for criterion-related validity and discriminant validity were examined using demographic, disease-specific, and general QoL questionnaires.

Results: The MVDQOL-BCI demonstrated strong internal consistency ($\alpha = 0.853$) and satisfactory test-retest reliability (ICC = 0.842). Criterion-related validity was confirmed with the Asian DQOL total score, EQ-visual analog scale score, short-form 36 total scores, 8 subscales, and HbA1c percentage ($p < 0.05$). Discriminant validity revealed better QoL was associated with females, higher education, higher income, shorter diabetes duration, and non-insulin therapy use.

Conclusions: The MVDQOL-BCI is a reliable and valid tool for assessing QoL in adult Mongolian patients with DM. Our findings support the extensive utilization of the MVDQOL-BCI and facilitates a deeper understanding of the impact of diabetes and its management on patient well-being.

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Introduction

In 2021, the global incidence of diabetes mellitus (DM) among individuals aged 20-79 years reached 536 million worldwide.[1] An increase to 783 million by 2045 has been forecasted, with an anticipated 68% surge in cases expected within Southeast Asia. In recent years, the prevalence of DM has been steadily rising in Mongolia, with a near two-fold increase in cases from 0.8 to 1.5 per 10,000 population reported between 2013 and 2022. This highlights a concerning trend in Mongolia's public health landscape over just one decade.[2]

Diabetes is a chronic metabolic disorder characterized by increased blood glucose levels that can result in progressive heart, blood vessel, eye, kidney, and nerve injury.[3] Upon diagnosis, patients initiate anti-diabetic therapy and adopt lifestyle changes aimed at mitigating the effects of diabetes,[4] including improvements in diet, weight, and physical activity engagement, quitting smoking, and monitoring blood glucose, lipids, and pressure. However, effective DM management can be a clinical challenge as it necessitates intricate alterations in patient behavior and lifestyle.[5-7] If untreated, patients become susceptible to various complications that can impact health outcomes and overall quality of life (QoL). DM

management ultimately aims to improve patient well-being through attentive medical care and diligent self-care behaviors.[8,9] Hence, QoL assessment is essential for evaluating treatment and care, as well as improving overall DM management. Disease-specific QoL tools are widely used as primary outcomes in clinical trials designed to measure changes in health-related QoL owing to their responsiveness to changes in health and ability to assess the impact of disease. Various diabetes-specific QoL measures have been introduced to measure the health-related QoL in individuals with diabetes.[10,11]

The Diabetes Quality of Life Brief Clinical Inventory (DQOL-BCI), formulated by Burroughs et al.[12] in 2004, is an assessment tool consisting of 15 questions based on the comprehensive 46-item Diabetes Quality of Life (DQOL) questionnaire.[13] The DQOL-BCI has demonstrated effectiveness comparable to that of the full DQOL questionnaire in predicting self-reported diabetes care behaviors and satisfaction with diabetes control. Extensive questionnaires can be impractical in clinical settings because of the time required for completion, which often conflicts with patient cooperation levels.[14-21] However, the DQOL-BCI can yield a comprehensive total health-related QoL score in approximately 10 min,[7,12] making it particularly valuable in clinical settings as it enables healthcare providers to swiftly identify patient concerns that might otherwise be overlooked during routine patient interactions and subsequently customize treatment strategies to address them.

The DQOL-BCI has gained broad acceptance in both clinical and research contexts and has been translated into eight languages: Iranian, Polish, Malaysian, Greek, Chinese, Indonesian, Urdu, and Turkish. To date, no Mongolian version of the DQOL-specific questionnaire has been developed. Given its proven utility and adaptability worldwide, the DQOL-BCI presents a promising tool for effective utilization in Mongolia. Therefore, the aim of this study was to assess the reliability and validity of the Mongolian version of the Diabetes Quality of Life Brief Clinical Inventory (MVD-QOL-BCI) in patients with type II DM (T2DM).

Materials and Methods

Ethics

This cross-sectional study was approved by the Biomedical Research Ethics Committee of the Mongolian National University of Medical Sciences (approval number 2020/3-01) and the Ethical Committee of Gunma University (approval number HS2022-267). Prior to data collection, patients who expressed their willingness to participate were presented with information about the study objectives and procedures, and informed consent was obtained. All participants were assured of their right to privacy and confidentiality. The study procedures adhered to the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments.

Participants

A sample size was determined by suggestion of 10 participants for every question in the instrument of the DQOL-BCI and possible data error was considered 30%. [22] There were 400 consent forms distributed to the eligible participants and a total of 234 patients agreed to participate in the study. Among these, 197 provided complete data for analysis and a further 88 agreed to a retest 4-6 weeks later. The patients were recruited from three hospitals in Ulaanbaatar: The Mongolia-Japan Teaching Hospital of the Mongolian National University of Medical Sciences, the Songino Khairkhan District Health Center, and the Bayangol District Health Center. The patients were approached while they were waiting to consult medical doctors and specialists in both the outpatient and inpatient departments of the designated hospitals. Data collection occurred between September 2021 and October 2022. The eligibility criteria were individuals aged ≥ 18 years with a diagnosis of T2DM confirmed ≥ 3 months before the study, receiving ongoing anti-diabetic treatment under the guidance of an endocrinologist, and with the ability to communicate and read the Mongolian language. Individuals with critical health conditions such as kidney failure, heart failure or cognitive impairments that could substantially affect their ability to accurately assess their health and QoL were excluded.

Measures

Demographic questionnaire

The following data were collected by questionnaire: age, sex, marital status, education, ethnicity, working status, monthly income, duration of T2DM, and type of medication used (insulin or non-insulin). The HbA1c percentages of all patients were collected from the medical records.

Diabetes Quality of Life Brief Clinical Inventory

The 15-item DQOL-BCI was presented in two different formats, each assessing distinct aspects of the participants' experiences with T2DM. The first format gauged the frequency of negative diabetes- or treatment-related impacts, with response options ranging from "never" to "all the time." The second format gauged the participant's treatment satisfaction and overall QoL, with response options ranging from "very satisfied" to "very dissatisfied." For each question, the participants assigned scores ranging from 1-5, where 1 indicated the highest level of satisfaction or lowest frequency of negative effects and 5 indicated the lowest level of satisfaction or highest frequency of negative effects. The total score attainable on the DQOL-BCI ranged from 15-75, with higher scores indicating lower QoL for patients with T2DM.

DQOL–BCI translation

The DQOL-BCI translation process adhered to the principles of good practice for the translation and cultural adaptation process for patient-reported outcome (PRO) measures framework[23] and consisted of the following ten steps to ensure the accurate translation, cultural adapta-

tion, and validation of the DQOL-BCI for use in the Mongolian context:

(1) Preparation: We identified the translation process and its components; established the rationale behind each step; designated responsible individuals as forward translators, backward translators, and expert team members, including linguists, endocrinologists, nurses, medical doctors, and original DQOL-BCI author; and recognized the risks associated with inadequate execution.
(2) Forward Translation: Two independent translators, one expert medical linguist, and one English-proficient endocrinologist, translated the DQOL-BCI from English into Mongolian, resulting in two separate Mongolian versions.
(3) Reconciliation: The expert committee collaboratively reviewed and resolved ambiguities, inconsistencies, and meanings to achieve a consensus.
(4) Back Translation: The Mongolian version was then back-translated into English by the medical linguistic translator and English-proficient endocrinologist.
(5) Back Translation Review: The translated versions were thoroughly examined and discussed by the study team. Discrepancies in the format, wording, syntax, meaning, and relevance were identified and resolved.
(6) Harmonization: The study team worked to harmonize the translations, aiming for a consensus regarding the accuracy and appropriateness of the content.
(7) Cognitive Debriefing: Comprehensibility of the translated questionnaire was achieved using a cognitive debriefing test involving 23 outpatients with T2DM who provided feedback for further refinement and represented diverse demographics.
(8) Cognitive Debriefing Results Review: The principal investigator reviewed the cognitive debriefing results and identified any necessary modifications to enhance the understanding of the questionnaire.
(9) Proofreading: The questionnaire was meticulously proofread to correct minor errors before creating the final version.
(10) Finalization: Prior to data collection, the team finalized the questionnaire by agreeing with each member of the study team.

During the translation process of Cognitive Debriefing Results Review: the following issues arose during discussions between the study team:

1. The response choice "neither" was not directly translated into Mongolian as "аль нь ч биш" was deemed too difficult for Mongolians to understand. Instead, the translation chosen was "Мэдэхгүй," which means "I don't know" in English.
2. Question 8, which asked about the participants' sexual life, was highlighted as sensitive due to potential cultural differences and personal discomfort. However, the decision was made to keep this question as it is considered an important indicator of diabetes-related QoL. If needed, investigators could provide relevant explanations or additional contexts to help the participants feel more comfortable answering the question.
3. To enhance understandability and sensitivity, the translation of Question 13 was revised. The original phrasing "Та нас барахаас хэр их айдаг вэ?" meaning "How often do you feel the need to pass out?" was replaced with "Танд ухаан балартан унах вий гэсэн зовнил хэр их тохиолддог вэ?" which translates to "How often do you worry about fainting?" This revision aimed to maintain the essence of the question while using a more relatable and culturally and emotionally sensitive context that may be easier for patients to understand.

External validity instruments

The following scales were used to test the criterion-related validity. All necessary permissions to utilize the instruments were obtained.

1. Asian Diabetes Quality of Life

The 21-item Asian DQOL scale was introduced by Coh et al. in 2014 to specifically address diverse linguistic nuances within Asian populations. This scale is available in three languages: English, Malaysian, and Chinese. The scale uses a 5-point rating system (1-5) to assess patient satisfaction across various dimensions related to diabetes and their overall QoL, with 1 representing "very dissatisfied" and 5 indicating "very satisfied." The cumulative Asian DQOL score ranges from 21-105, with higher scores indicating better QoL. As the Asian DQOL questionnaire is not available in Mongolian, we translated the text by forward-backward steps. Final version was discussed by study team and shown good internal consistency based on data collected from a pilot group consisting of 23 participants using Cronbach's alpha coefficient ($\alpha = 0.914$).

2. 36–item Short Form Survey

The 36-item Short Form Survey (SF-36 version 1.0) was developed by the RAND Corporation in 1992 as a set of universally applicable, cohesive, and user-friendly measures for assessing QoL. The SF-36 is compartmentalized into eight distinct subscales, each gauging a different aspect of well-being: physical functioning, limitations in daily activities due to physical health, limitations in daily activities due to emotional issues, levels of energy or fatigue, emotional well-being, social functioning, pain, and overall health perception. It also includes a single item that provides an indication of perceived changes in health over time. In the SF-36 questionnaire, respondents are asked to rate their experiences with each item on a scale ranging from 0-100, with higher scores reflecting a more favorable health status and QoL. As the initial SF-36 (version 1.0) was unavailable in Mongolian, we followed the forward-backward

translation procedure and final version was encouraging internal consistency (α=0.806), suggesting that the translated version could be reliably used for further research.

3. EQ-5D-5L

The 5 level EQ-5D version (EQ-5D-5L) was introduced by the Euro Qol Group in 2009. It consists of two pages: the EQ-5D descriptive system and the EQ visual analog scale (EQ-VAS). The EQ-5D descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels: no, slight, moderate, severe, and extreme problems. The patient indicates their health status by ticking the box adjacent to the most appropriate statement in each of the five dimensions. As the EQ-5D-5L value set is not available in Mongolian, the Japanese value set was selected as an alternative. EQ-5D-5L index scores range from -0.59 to 1, where 1 is the best possible health state and 0 index score indicates death and negative values such as -0.59 indicate low QOL level.

The EQ-VAS records the patient's self-rated health on a vertical visual analog scale, where the endpoints are the "best" and "worst" health imaginable. The participant marks an X on the scale to indicate their health and writes the number in a box. As the EQ-5D-5L was unavailable in Mongolian, we translated it in forward-backward procedure and its final version after study team discussion, found strong internal consistency (α=0.888), highlighting the reliability of the Mongolian EQ-5D-5L version used in our validation study.

Statistical analysis

Descriptive statistics were used to analyze the frequencies and percentages, means, standard deviations of parametric variables, and maximum and minimum values. The Kolmogorov-Smirnov test was used to check the normality of distribution, with the significance level set at $p<0.05$. MVDQOL-BCI reliability was evaluated by testing for internal consistency using Cronbach's alpha analyses, with scores ≥ 0.7 considered satisfactory. The test-retest reliability among the 88 data points was checked using the intraclass correlation coefficients (ICC) of the total scores using a single-measurement, absolute agreement, two-way mixed model. Correlation values of ICC$<$0.5, 0.5$\leq$ICC$<$0.75, 0.75$\leq$ICC$<$0.9, and ICC$>$0.9 indicated poor, moderate, good, and excellent correlation, respectively. MVDQOL-BCI accuracy was evaluated by examining floor and ceiling effects that are considered to be present if more than 15% of respondents achieve the lowest or highest possible score, respectively.[24]

Scale validity was investigated through content, criterion-related, and discriminant validity. Pearson's correlation coefficient was used to verify the criterion-related validity of the MVDQOL-BCI using the Asian DQOL, EQ-5D-5L Index value, EQ-VAS, SF-36 and its subscales, and HbA1c percentage. Correlation values (r) of 0.3$\leq$r$<$0.5, 0.5$\leq$r$<$0.7, and 0.7$\leq$r$<$0.9 indicated moderate, good, and excellent correlation, respectively.

MVDQOL-BCI discriminant validity was further evaluated based on various demographic factors, namely sex, marital status, education, ethnicity, employment status, monthly income, and diabetes-related characteristics such as diabetes duration and insulin treatment. After ensuring normal distribution and homogeneity of variance, we utilized independent sample t-tests and one-way analysis of variance (ANOVA) to compare the means of two and three independent groups, respectively, and performed Bonferroni correction for multiple comparisons. All statistical analyses were performed using IBM SPSS (version 27.0; IBM Corp., Armonk, NY, USA).

Results

Participant characteristics

In total, we analyzed data from 197 patients with T2DM, consisting of 87 (44.2%) males and 110 (55.8%) females, with an average age of 51.67±12.21 years (range: 21-83 years). The mean duration of diabetes was 7.6±6.0 years (range: 3 months-32 years). The participants were grouped according to duration after diabetes diagnosis as follows: "< 1 year," "1year-5 years," and "> 5 years". The sociodemographic characteristics of the study population are presented in Table 1.

Table 1 Participant characteristics (n=197)

		Number	%
Sex	Male	87	44.2
	Female	110	55.8
Marital status	Living with partner	172	87.3
	Single or living alone	25	12.7
Education	High school	110	55.8
	Higher education	87	44.2
Ethnicity	Khalkh	169	85.8
	Other	28	14.2
Work	Working	92	46.7
	Not working	23	11.7
	Retired	82	41.6
Monthly income	<1.2 million tögrög#	104	52.8
	1.2-2.5 million tögrög#	54	27.4
	>2.5 million tögrög#	39	19.8
Duration of iabetes	<1 year	21	10.7
	1 year-5 years	62	31.5
	>5 years	114	57.9
Antidiabetic therapy	Insulin	73	37.1
	Non-insulin	124	62.9
		Mean	SD
Age		51.6	12.2
HbA1c		9.12	1.89

Abbreviations: SD, standard deviation; HbA1c, glycated hemoglobin.
Mongolian currency: 3477 tögrög is equal to 1 US dollar, 1.2 million tögrög is equal about 345 US dollars, 2.5 million tögrög is equal about 719 US Dollars (as of September 2023)

Table 2 Descriptive statistics, Cronbach's alpha coefficients, and test-retest intraclass coefficients of the MVDQOL-BCI total score (n=197)

Components	Number of items	Mean	SD	Min	Max	Floor n (%)	Ceiling n (%)	Cronbach's alpha	Test-retest ICC (n=88)
DQOL-BCI total score	15	40.34	8.67	21.00	64.00	0 (0)	0 (0)	0.853	.842

Abbreviations: MVDQOL-BCI, Mongolian version of the Diabetes Quality-of-Life Brief Clinical Inventory; SD, standard deviation; ICC, intraclass coefficient; max, maximum; min, minimum.

Reliability

The Cronbach's alpha coefficient of the MVDQOL-BCI was 0.85, indicating good reliability. As illustrated in Table 2, the test-retest reliability of the MVDQOL-BCI total score was deemed satisfactory after ICC evaluation.

Floor or ceiling effects

The total MVDQOL-BCI score ranged from 15-75 and the average MVDQOL-BCI scores were 40.34±8.67 (range: 21.0-64.0). Hence, no floor or ceiling effects were observed.

Table 3 Correlation between the MVDQOL-BCI, Asian DQOL, EQ-5D, EQ-VAS, HbA1c, SF-36, and SF-36 subscale scores (n=197)

	MVDQOL-BCI total	
	Pearson's correlation	*P* value
Asian DQOL total	−0.621	0.001**
EQ-5D-5L Index value	−0.415	0.001**
EQ-VAS score	−0.171	0.016*
HbA1c	0.312	0.001**
SF36 total and subscales		
SF36 total	−0.666	0.001**
Physical functioning	−0.256	0.001**
Role limitations due to physical health	−0.460	0.001**
Role limitations due to emotional problems	−0.445	0.001**
Energy/fatigue	−0.533	0.001**
Emotional well-being	−0.533	0.001**
Social functioning	−0.440	0.001**
Pain	−0.503	0.001**
General health	−0.539	0.001**

**$p<0.01$, *$p<0.05$

Abbreviations: MVDQOL-BCI, Mongolian version of the Diabetes Quality-of-Life Brief Clinical Inventory; EQ-5D-5L, Euro quality of life Five Dimension Five level questionnaire; VAS, visual analog scale; HbA1c, glycated hemoglobin; SF-36, 36-item Short Form Survey

Validity

Criterion-related validity

MVDQOL-BCI total scores were strongly negatively correlated with Asian DQOL total scores (r=−0.621) and SF-36 total score (r=−0.666) and its subscale scores, moderately correlated with EQ-5D-5L Index value (r=−0.415), weakly correlated with EQ-VAS scores (r=−0.171). In contrast, MVDQOL-BCI total score positively moderately correlated with the HbA1c levels (r=0.312) (Table 3).

Discriminant validity

Discriminant validity revealed significant differences in MVDQOL-BCI total score based on sex, education, monthly income, duration of diabetes, and insulin and non-insulin treatment groups (Table 4). In contrast, no significant differences in terms of marital status, ethnicity, or work status were found.

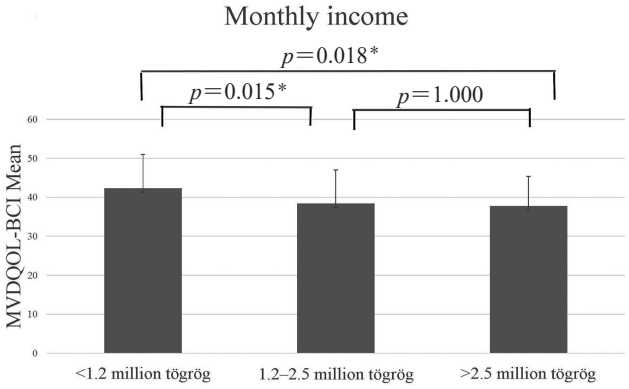

Fig. 1 Association between mean MVDQOL-BCI score and monthly income with Bonferroni multiple comparisons (n=197)

Abbreviations: MVDQOL-BCI, Mongolian version of the Diabetes Quality-of-Life Brief Clinical Inventory.

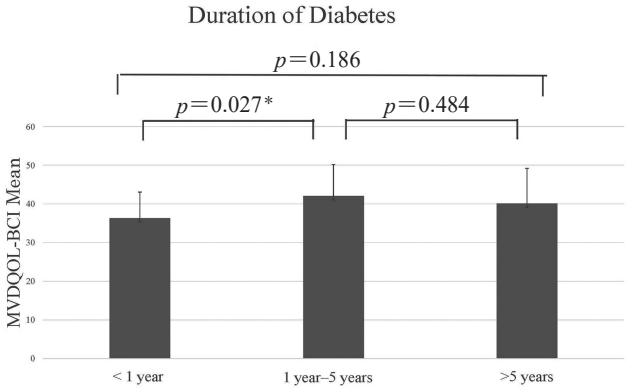

Fig. 2 Association between mean MVDQOL-BCI score and the duration of diabetes with Bonferroni multiple comparisons (n=197)

Abbreviations: MVDQOL-BCI, Mongolian version of the Diabetes Quality-of-Life Brief Clinical Inventory.

Table 4 Comparison of the MVDQOL-BCI total scores based on demographic factors and diabetes status (n=197)

		Mean	SD	*P* value	Test
Sex	Male	42.41	9.22	0.003**	Independent samples t-test
	Female	38.70	7.87		
Marital status	Married	40.17	8.62	0.483	Independent samples t-test
	Single or living alone	41.48	9.12		
Education	High school	41.85	9.37	0.006**	Independent samples t-test
	Higher education	38.44	7.31		
Ethnicity	Khalkh	40.40	8.93	0.805	Independent samples t-test
	Other	39.96	7.03		
Work	Working	40.61	8.05	0.345	One-way ANOVA
	Not working	42.35	10.01		
	Retired	39.48	8.94		
Monthly income	＜1.2 million tögrög#	42.32	8.65	0.003**	One-way ANOVA
	1.2-2.5 million tögrög#	38.37	8.67		
	＞2.5 million tögrög#	37.79	7.55		
Duration of diabetes	＜ 1 year	36.33	6.73	0.030*	One-way ANOVA
	1 year-5 years	42.05	8.14		
	＞5 years	40.15	9.06		
Antidiabetic therapy	Insulin	43.25	8.62	0.001**	Independent samples t-test
	Non-insulin	38.63	8.27		

**$p<0.01$, *$p<0.05$

Abbreviations: MVDQOL-BCI, Mongolian version of the Diabetes Quality-of-Life Brief Clinical Inventory; HbA1c, glycated hemoglobin; SD, standard deviation; ANOVA, analysis of variance.

Mongolian currency: 3477 tögrög is equal to 1 US dollar, 1.2 million tögrög is equal about 345 US dollars, 2.5 million tögrög is equal about 719 US Dollars (as of September 2023)

As shown in Fig. 1 and 2, the results indicate significant differences in QoL between specific groups in terms of monthly income and the duration of diabetes. However, no significant difference was found between individuals with income levels of 1.2-2.5 million tögrög and ＞2.5 million tögrög or diabetes durations of ＜1 year and ＞5 years.

Discussion

This study investigated the reliability and validity of the 15-item MVDQOL-BCI for assessing QoL among patients with T2DM in a Mongolian context by testing the internal consistency of the overall and test-retest consistency of scores over time, as well as performing a criterion-related, and discriminant validity assessments. Our results highlight the suitability and accuracy of the MVDQOL-BCI for gauging QoL in Mongolian patients with diabetes, making it a robust tool for use in future research and clinical contexts. The original DQOL-BCI did not distinctly categorize items into subscales and the core instrument, which comprised 46 items from DQOL by Diabetes Control and Complications Trial, was categorized into four subscales: satisfaction, impact, social and vocational worry, and diabetes-related worry.[12,13] Therefore, we propose employing the MVDQOL-BCI version without subscales in all relevant settings.

Reliability

The MVDQOL-BCI Cronbach's alpha coefficient was 0.853, which was similar to the original DQOL-BCI version (0.850)[12] and higher than that of the Iranian (0.750), Polish (0.760), Malaysian (0.703), Indonesian (0.735), and Chinese (0.731) versions, but lower than that of the Urdu (0.866), Turkish (0.90), and Greek (0.950) versions. Furthermore, the MVDQOL-BCI test-retest reliability, estimated using ICC from 88 participants retested after a 4-6-week interval, was 0.842, which is higher than that of the Iranian (0.801), Malaysian (0.860), and Urdu (0.850) versions, but lower than that of the Polish (0.960) and Turkish (0.980) versions. Overall, the MVDQOL-BCI reliability assessment revealed favorable results.[14-21]

Criterion-related validity

Criterion-related validity was assessed using the Asian DQOL as a disease-specific measure[10] and the SF-36 and EQ-5D-5L as general QoL questionnaires. A significant emerging trend indicated that higher HbA1c percentages were negatively associated with higher QoL.[25] High HbA1c levels indicate poor glycemic control, which can lead to various diabetes-related complications and negatively affect the QoL of individuals with diabetes. Thus, individuals with better T2DM management experience better QoL.

Our results highlighted negative correlations between the MVDQOL-BCI total score and various parameters, specifically Asian DQOL total score and SF-36 total score and subscale scores, suggesting that as

MVDQOL-BCI-measured QoL decreases, other QoL measures tend to decrease as well. Among them, Asian DQOL-BCI, SF-36 total score, and SF-36 subscales of general health correlated most strongly with MVDQOL-BCI total score, followed by energy/fatigue and emotional well-being subscales.

We found a moderate-level association between the total score of MVDQOL-BCI and the EQ-5D-5L Index value set ($r=-0.415$, $p=0.001$). However, as the EQ-5D-5L Index value set was unavailable in Mongolian, an alternative Japanese Index value set was used. This substitution may have influenced the strength of the correlation observed.

The EQ-5D, a widely employed general health-related quality of life questionnaire, proves effective in capturing the burden experienced by patients with T2DM and is accessible in 159 languages.[26] Despite the absence of reported correlations between its English version and the DQOL-BCI, analogous correlation trends are evident in validation studies of the DQOL-BCI conducted in various languages. In the pursuit of criterion-related validity for the DQOL-BCI in Malaysian and Turkish versions, the three-level generic tool EQ-5D-3L serves as an alternative to the EQ-5D-5L. The Malaysian DQOL-BCI demonstrated a negative moderate correlation with EQ-5D-3L ($r=-0.329$, $p=0.003$),[20] a trend similarly observed in the Turkish version of the DQOL-BCI ($r=-0.220$, $p=0.008$).[14] In a study utilizing the Chinese version, EQ-5D-5L was employed to assess the correlation with DQOL-BCI, yielding a comparable trend of moderate-level association ($r=-0.364$, $p=0.0001$).[21]

We also revealed an association between the total score of MVDQOL-BCI and the HbA1c percentage. As the HbA1c percentages increased, indicating deteriorating blood glucose control and poor diabetes management, there was an increase in the MVDQOL-BCI score. This indicates that worsening blood glucose control is linked to a decrease in the quality of life as measured by the MVDQOL-BCI. However, the small range of HbA1c percentages used in the study could have influenced the strength of the correlation, which was moderate. This finding is similar to the DQOL-BCI Malaysian version.[20]

The weakest correlation was observed between the MVDQOL-BCI and EQ-VAS scores. This may be attributed to the relative simplicity of the EQ-VAS score compared with other measures used in the study. EQ-VAS is a single visual analog scale that asks individuals to rate their overall health on a scale from 0 to 100, where 0 represents the worst health imaginable and 100 represents the best health imaginable. In the Malaysian version study, the correlation was strong ($r=-0.507$, $p=0.0001$),[20] indicating a robust relationship between the two measures. Similarly, the Chinese version demonstrated a substantial negative correlation ($r=-0.514$, $p=0.0001$),[21] reinforcing the consistency of this trend. In contrast, the Turkish version displayed a relatively lower level of correlation, albeit still significant ($r=-0.270$, $p=0.0001$).[14] This single-item measure may not capture the nuances of diabetes-related quality of life as comprehensively as multi-item questionnaires such as the Asian DQOL or SF-36. The criterion-related validity demonstrated the association between the MVDQOL-BCI total score and various QoL-related parameters in individuals with T2DM.

Discriminant validity

This study revealed a significant association between the MVDQOL-BCI and other demographic and diabetes-related metrics. Unlike previous studies,[27,28] our findings suggest that marriage, ethnicity, and working status did not exert a significant influence on the MVDQOL-BCI measured QoL.[25,26] It is essential to note that similar outcomes are also plausible in certain studies such as marital status,[14] ethnic minority status[32] and unemployment[33] do not correlate with the diabetes quality of life, necessitating further clarification research in Mongolia.

Our data indicated that females exhibited a higher quality of life. Existing literature presents conflicting views, with some studies asserting that women with diabetes experience a superior quality of life,[29,32] while others revealed a results in favor of men having better quality of life, improved diabetes management, and more effective with coping with diabetes complications.[27,28] This discrepancy may be attributed to variations in treatment modalities and socioeconomic parameters. Our study also found a positive association between higher education levels and a superior quality of life. Numerous studies support this, emphasizing that individuals with higher education tend to demonstrate stronger treatment adherence and an enhanced health-related quality of life due to their positive health outlook and greater attention to treatment management.[25-28]

Conversely, our results indicated that lower monthly income was linked to a poorer quality of life. The majority of studies align with this, highlighting that higher-income families generally enjoy a better quality of life. Economic status significantly contributes to the burden on individuals who must allocate substantial amounts for their treatment.[33,34] Based on our study the duration of diabetes may make a difference in quality of life among T2DM. Consistent with prior research, a prolonged duration of diabetes was associated with a lower quality of life, possibly stemming from a decline in patient attitude and adherence to prescribed treatment regimens.[25,27,34]

According to our study, patients under insulin treatment were more likely to report a lower quality of life. Daily insulin injections can induce physical discomfort, heighten anxiety about insulin dependency, impede social interactions, and negatively affect mental health.[30-34] Notably, our findings align with similar validation studies of DQOL-BCI in other cultural contexts, such as the Turkish and Iranian versions, where characteristics like a short duration of 1-5 years, high income, and non-insulin use correlated positively with high QoL scores.[14,18] These consistencies support the cross-cultural applicability of MVDQOL-BCI.

The assessment of discriminant validity in this study supports the utility of the MVDQOL-BCI as a valid

instrument for assessing QoL among patients with diabetes in Mongolia. Although certain demographic factors did not show significant associations with MVDQOL-BCI scores, other factors consistently demonstrated correlations, affirming the ability of this method to differentiate between various QoL experiences within this specific patient population.

Study advantages

First, by conducting this study in the urban setting of Ulaanbaatar, which is the largest city in Mongolia, the researchers were able to capture a diverse and representative sample of participants from various backgrounds and demographics owing to the high population density, making the findings more applicable to a broader population. Second, the inclusion of participants who had undergone HbA1c testing, which is a crucial indicator of long-term blood glucose control in patients with diabetes, facilitated the accurate and comprehensive assessment of T2DM management and its impact on QoL. Lastly, all participants were under the follow-up care of an endocrinologist and received specialized medical attention and guidance in managing their diabetes, which enabled us to obtain accurate results.

Study limitations

First, this study focused solely on patients with T2DM, which limits the applicability of our results and may not fully capture the diversity of experiences and outcomes among different populations with diabetes. Hence, our findings should be interpreted within the context of T2DM. Second, no exploratory factor analysis (EFA) was performed during validation assessment owing to the nature of the DQOL-BCI. Unlike instruments with multiple subscales designed to assess distinct dimensions, the DQOL-BCI is a unidimensional tool intended to capture the overall QoL in individuals with diabetes and hence lacks the subscale structure that typically necessitates EFA. Longitudinal validation studies should be conducted to further explore MVDQOL-BCI consistency and provide insights into how the instrument captures changes in diabetes-related QoL over an extended period. Moreover, future studies should widen their scope to include diverse populations, including type 1 DM and gestational diabetes.

Conclusion

MVDQOL-BCI was found to be a valid and reliable tool for assessing patient concerns and providing valuable insights into the QoL of individuals with T2DM in Mongolia. This study paves the way for the extensive utilization of the MVDQOL-BCI in patient-reported outcomes research and facilitates a deeper understanding of the impact of diabetes and its management on patient well-being. Furthermore, it opens avenues for the development and evaluation of targeted interventions aimed at enhancing the QoL for individuals with T2DM in Mongolia. Lastly, the MVDQOL-BCI can be readily employed in clinical settings for the benefit of both healthcare providers and patients.

Statements and declarations

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No funding was received for conducting this study.

Competing interests

The authors have no competing interests to declare that are relevant to the content of this article.

Compliance with ethical standards

thical approval was obtained from the Biomedical Research Ethics Committee of the Mongolian National University of Medical Sciences (approval number 2020/3-01) and the Ethical Committee of Gunma University (approval number HS2022-267). The study procedures adhered to the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments or other comparable ethical standards established for the involvement of human participants.

Informed consent

Informed consent was obtained from participants prior to data collection.

Data availability

Data to support the findings of this study are available upon reasonable request from the corresponding author.

Authors'contribution

Conception and design were performed by Dorjderem Choijiljav, Enkhjargal Yanjmaa, and Hiromitsu Shinozaki. Translation was performed by Dorjderem Choijiljav, Enkhjargal Yanjmaa, Shota Ogawa, Naidankhuu Batgerel, Bulgan Munkhtur, Thomas E. Burroughs, and Hiromitsu Shinozaki. Data were acquired by Dorjderem Choijiljav, Enkhjargal Yanjmaa, and Bulgan Munkhtur. Statistical analyses were conducted by Dorjderem Choijiljav, Yuki Ideno, Shota Ogawa, and Hiromitsu Shinozaki. The first draft of the manuscript was written by Dorjderem Choijiljav and Hiromitsu Shinozaki. All authors critically revised and approved the final version of the manuscript.

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