Validity and Reliability of Quality-of-Life Scale for Iraqi Diabetic Patients Among Type 1 Diabetes Mellitus Patients

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ABSTRACT

Diabetes mellitus significantly impacts life. Evaluating quality of life (QOL) is essential for diabetes management; there are many tools to assess QOL. However, no validated instruments are currently designed for Iraqi patients with type 1 diabetes (T1D). To assess the validity, reliability, and hence suitability of QOL scale for diabetic patients (QOLSID) for use among Iraqi patients with T1D. A cross-sectional study conducted at Faiha Specialized Diabetes, Endocrine and Metabolism Center in Basrah, Iraq, from February 17th to May 29th, 2025. A convenient sample of 100 Iraqi patients diagnosed with T1D completed the paper based QOLSID. Internal consistency was assessed using Cronbach's alpha. Construct validity was checked by correlating total scale score with the level of glycosylated hemoglobin (HbA1c). For test-retest reliability, 37 returned back to fill the questionnaire. The tested scale exhibited an acceptable internal consistency (Cronbach's alpha = 0.630). For test-retest values, the correlation for the overall total QOLSID scores was 0.422 (P = 0.020). A significant inverse correlation was found between QOLSID score and HbA1c (Spearman's ρ = −0.311, P = 0.002). This correlation was statistically significant across the entire cohort of patients with T1D, encompassing both adolescent and adult age groups. Using a median cutoff point, the results demonstrated a significant ability to distinguish between T1D patients based on their HbA1c levels and the presence of diabetes-related complications. The QOLSID questionnaire is a valid and reliable tool for evaluating the QOL of T1D patients in Iraq.

Keywords: Quality of life; QOLSID validity and reliability; Type 1 diabetes; Iraq.

INTRODUCTION

Type 1 diabetes (T1D) is a chronic disease that mostly affects children and adolescents less than 20 years old; however, it can occur at any age[1,2]. It characterized by autoimmune destruction of the insulin-secreting beta cells of the pancreas, producing absolute insulin deficiency and hyperglycaemia[3]. Therefore, patients living with T1D can suffer from acute (diabetic ketoacidosis) and long term complications (macro and microvascular)[4]. Long life insulin therapy along with life style modification (i.e. healthy dietary habits and physical activity) is necessary for T1D patients to maintain their lives and avoid acute and long-term complications[5]. Additionally, frequent blood glucose monitoring and insulin adjustments throughout daily life are necessary for the appropriate management of T1D[6,7]. In this regard, the disease itself and its treatment carry a great impact on the life and well-being of both patients and their families[8-10].

Quality of life (QOL) is a significant patient-reported outcome that reflects a person's subjective assessment of their general well-being, level of satisfaction with their daily life, capacity to engage in work and leisure activities, emotional state, and social interaction[11]. Both positive and negative effects on QOL can result from insulin therapy. While it generally improves glycaemic control, lowers diabetic control, and improves health-related QOL[12], insulin injections can create a challenge by making daily life activities inconvenient, painful, and burdensome[13]. Hypoglycaemic episodes, which are occasionally brought on by insulin treatment, also lower QOL due to the actual occurrences as well as the anxiety they cause[14]. Advancements in insulin treatment strategies over recent years—such as insulin analogues, advanced delivery devices (pens and pumps, sensors and automated systems—aim to improve glycaemic control and reduce hypoglycaemia[15]. Such advancement in treatment of T1D was found to be effective in improving the QOL of patients with T1D, especially for children and adolescents[16-18].

Assessing QOL aids professionals in identifying the most appropriate treatment for T1D patients by helping them comprehend how T1D and its treatment affects a patient's social, psychological, and physical facets of everyday functioning[19].Therefore, QOL assessment is crucial as part of T1D management[20]. To yield accurate and meaningful results that can influence treatment, a valid and trustworthy evaluation of QOL in T1D is required[21]. Many scales measure QOL in diabetic patients; however, the length of the questionnaire limits patient response rates in most cases. In addition, variation in culture and social characteristics of the involved population emphasizes the need for a specific, brief survey suitable for Iraqi patients. A quality of life scale for Iraqi DM patients (QOLSID) was the only available tool to assess QOLfor Iraqi diabetic patients; however, it was validated among patients with type 2 diabetes[22].

Taken into account the differences in disease management, symptomatology, and psychosocial impact, between type one and type 2

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diabetes mellitus[23], the direct adoption and use of QOLSID among T1D may be unacceptable. Therefore, the current study aims to evaluate the reliability and validity of the existing QOLSID questionnaire among patients with T1D.

METHODS

Study Design: This cross-sectional study included Iraqi patients diagnosed with T1D attending the Faiha Specialized Diabetes, Endocrine and Metabolism Center in Basrah, Iraq. The study was continued from the 17th of February 2025 to the 29th of May 2025.

Study sample and participants: According to the "rule of thumb" for psychometric validation, which states that should be at least 10 participants for each item on the scale, a sample of 100 participants was the target in the current study (24).A convenient sample of patients with confirmed diagnosis of T1D for at least 12 months and aged ≥ 12 years, who start self-management, were considered eligible to participate in this study. Patients with major psychiatric disorders, pregnancy, physical disability, or other chronic illnesses affecting QOL assessment, including cancer and rheumatologic disorders were excluded from participation in the present study.

Only patient who accepted to provide their verbal informed consent were included in this study and asked to fill in the QOLSID [Appendix A]. A minimally required sample for test retest reliability is 30 based on survey validation standards[25-27]. By taking into account high drop-out rate among Iraqi patients[28], 50 participants were informed about the need to refill the scale 2 weeks later; however, only 37 returned back to fill the questionnaire.

Data collection: All participants were given a paper based QOLSID to fill in. For participants who informed about the need for re-testing, they filled in the questionnaire twice. Glycosylated hemoglobin (HbA1c) was measured for all patients only at the start of the study. It was measured using HPLC method by Variant 11 (Bio-Rad, USA) apparatus.

Statistical Analysis: Statistical analysis were conducted using the Statistical Package for the Social Sciences (SPSS) software, (version 17). Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequency (percentage). Data normality was assessed using the Shapiro-wilk test. The internal consistency of the scale was measured with Cronbach's alpha coefficient. The tool is considered to have acceptable reliability when a Cronbach's alpha score is greater than 0.6[29] and good if exceeds 0.7[30] with a corrected item-total correlation greater than 0.2[31] For test re test reliability, Spearman's rho correlation was used, where it is poor (<0.2); fair (0.21-0.40); good (0.41-0.60); very good (0.61-0.80); and excellent (0.81-1.0) (32). A P value of< 0.05 considered statistically significant differences.

RESULTS

Participant Characteristics

The participated patients had an average age of 23.10 ± 8.71 years and were 56% male and 44% female. The mean duration of diabetes was 9.18 ± 6.71 years. Most patients (92%) were using old types of insulin (regular and NPH insulin). Diabetic complications were present in 73% of participated patients. Details about demographic and clinical data of participants are shown in Table 1.

Psychometric properties of the QOLSID

Reliability analysis: The assessment of QOLSID's internal consistency revealed a Cronbach's alpha of 0.630. It can be increased to 0.638 if item 2, and to 0.635 if item 3 is deleted. The corrected item-total correlations for all items of the scale, except items 2 and 3, were more than 0.2 as in Table 2. For test-retest values, the correlation for the overall QOLSID's total scores was 0.422 (P = 0.020). When examining the specific items within the QOLSID, none, except the last item, showed significant differences between the test and retest assessments (P > 0.05), indicating acceptable stability over time as in Table 3.

Table 1. Demographic characteristics of study participants

Parameter	Value
Age years[mean ± SD (range)]	23.10 ± 8.71 (12-51)
Gender	
Male, n (%)	56 (56%)
Female, n (%)	44 (44%)
Duration of DM years mean ± SD (range)	9.18± 6.71 (1-33)
Treatment	
Regular insulin and NPH insulin n (%)	92 (92%)
Mixtard insulin n (%)	7 (7%)
Novorapid and lantus n (%)	1 (1%)
Education	
Primary n (%)	23 (23%)
Secondary n (%)	62 (62%)
College n (%)	15 (15%)
Diabetic complication	
Absent n (%)	27 (27%)
Present n (%)	73 (73%)
Neuropathy n (%)	62 (62%)
Retinopathy n (%)	33 (33)
Hypertension n (%)	6 (6%)
HbA1c (%) mean ± SD	9.63±2.06
HbA1c	
Poor control (≥7) No (%)	89 (89%)
Good control (<7) No (%)	11 (11%)

Concurrent validity

The QOLSID total scores showed a significant inverse correlation with HbA1c (Spearman's ρ = −0.311, P = 0.002); consistent across all age groups in T1D both adolescent and adult (Table 4). While all QOLSID domains were correlated positively with total scores, only the satisfaction and overall health domain had a significantly negative correlation with HbA1c (Table 5).

Cut-off point of QOLSID

According to the original QOLSID cutoff point score, there are only two participants with scores ≥32.5. Therefore, a median value (21.5) was chosen as cutoff point. The new cutoff point was shown to be significantly effective in discriminating between T1D patients by their HbA1c level and by the presence of diabetes complication among them. Age and duration of DM was longer among patients with poor QOL than those with good QOL according to the new set cutoff point; however, this difference fail to achieve statistical significance. Details are shown in table 6.

DISCUSSION

The results of the current study demonstrated that the used tool (QOLSID) possesses acceptable internal consistency and concurrent validity. Additionally, the results of the test-retest analysis further support the questionnaire's stability over time.

The Cronbach's alpha values 0.630 of the scale indicate moderate internal consistency, while not ideal but within the accepted threshold[24,33]

Table 2. Internal consistency of QOLSID

Parameter	Corrected Item -Total Correlation	Cronbach's Alpha if Item Deleted
Q (1)	0.368	0.588
Q (2)	0.147	0.638
Q (3)	0.14	0.635
Q (4)	0.429	0.572
Q (5)	0.206	0.624
Q (6)	0.361	0.591
Q (7)	0.284	0.608
Q (8)	0.396	0.582
Q (9)	0.393	0.582
Q (10)	0.234	0.617

Table 3. The reliability of QOLSID after re-testing

Parameter	Z score	P value
Q (1)	-0.739	0.46
Q (2)	-0.538	0.591
Q (3)	-1.236	0.216
Q (4)	-0.147	0.883
Q (5)	-1.813	0.07
Q (6)	-1.29	0.197
Q (7)	-0.963	0.335
Q (8)	-0.745	0.456
Q (9)	-0.494	0.621
Q (10)	-2.693	0.007
Total score correlation	-0.422	0.02

Table 4. Association of QOLSID with HbA1c (Concurrent validity)

Parameter	Correlation coefficient	P value
All included patients (n=100)	-0.311	0.002
Adults (≥18 years old) (n=68)	-0.281	0.02
Adolescents (12-19 years old) (n=42)	-0.385	0.012

Table 5. Associations between the score of different QOLSID domain, HbA1c levels, and overall QOLSID scores

Domain	**With HbA1c**		**With total Scale score**	
Domains	**Correlation coefficient**	**p-value**	**Correlation coefficient**	**p-value**
Satisfaction (1-4, 10) Normal	-0.287	0.004	0.828	0
Psychological (6, 7) Abnormal	-0.053	0.601	0.601	0
Social (5) Abnormal	0.002	0.987	0.298	0.003
Overall health (8,9) Abnormal	-0.277	0.005	0.701	0

Table 6. Discriminatory ability of QOLSID cut-off point

Parameter	Poor QOL (<21.5)	Good QOL (≥21.5)	P value
HBA1c mean ± SD	10.21±2.11	9.05±1.85	0.004
Age (in years) mean ± SD	24.24±8.23	21.96±9. 11	0.054
Presence of complications n (%)	42 (84%)	31 (62%)	0.013
Duration of disease (in years) mean ± SD	9.73±6.14	8.64±7.26	0. 143
Gender			
Male n (%)	29 (58%)	27 (54%)	0.687
Female n (%)	21 (42%)	23 (46%)	

indicating that the items are related and measure similar construct. This modest internal consistency (Cronbach's alpha) may be explained by limited number of items in the original QOLSID, since it is well known that Cronbach's alpha typically rised as more items are included in the scale[34]. Similarly, several other scales used among diabetic patients have reported Cronbach's alpha values within a comparable range (>0.6) and are considered reliable tools[35,36]. Cronbach's alpha slightly increases to 0.638 by excluding the second item and to 0.635 if third item is excluded. These two items showed a low corrected item-total correlation (< 0.2). However item 2 was important for T1D and related to daily life activity especially if patients or caregiver has insufficient knowledge about insulin therapy[37] and thus it was not excluded. Similarly, other scales for diabetes mellitus patients did not exclude items with low corrected item-total correlations, and excluding such items resulted in only a minor increase in the overall Cronbach's alpha, provided the items were deemed to be important[38].

The finding of the current work indicated that the total QOLSID score was positively and significantly correlated after the 2-week re-testing period. Additionally, there was non-significant difference in test-retest values for any single item in the QOLSID except for item 10. The variation in the re-test results for item 10 may be attributed to the nature of this item, which assesses patients' satisfaction with healthcare services. Such services can fluctuate over time in Iraqi hospitals and medical centers due to factors like interruptions in drug supply and physician rotation. Additionally, the competence and communication skills of physicians providing care may vary significantly between visits[39]. While these factors may contribute to the observed variability, it is highly recommended to investigate the underlying sources of instability related to item 10 and to identify potential improvement measures through direct interviews with patients. By taking into account the current study results QOLSID can be considered to have an acceptable stability over time (i.e., good test-retest reliability).

The result of the present study also demonstrate a significant and impactful negative correlation between total QOLSID score and HbA1c among different age group of patient with T1D. Furthermore, the results of the present study revealed notable associations between the QOLSID domain scores (Satisfaction, Psychological, Social, Overall health) and total QOLSID score. On the other hand, two of the QOLSID domain scores (Satisfaction and total health) were significantly and inversely correlated with HbA1c values; such result were also obtained during the validation of the original scale among type 2 DM patients[22]. However, unlike the results in T2DM patients, the psychological and social domains were not significantly correlated with HbA1c levels in our study. One possible explanation for this discrepancy is the difference in age between T1DM and T2DM patients. Most T1DM patients tend to be younger and typically receive substantial social support from their families, which may mitigate the negative psychological effects associated with poor glycemic control[40]. All of the above obtained results confirm the validity of QOLSID among patient with T1D.

Regarding the cutoff point of the QOLSID, a median value was employed, which is an acceptable and widely used method in the literature[41,42]. The determined cutoff point proved to be effective, as evidenced by its ability to distinguish between T1DM patients based on their HbA1c levels and the presence of diabetes complications. Similarly, QOLSID was significantly different between T2DM patients with good versus poor glycemic control, as well as between patients with and without comorbid conditions[22].

Limitations of this study include moderate sample size and single center recruitment of the patients, which may limit generalizability. The broad age range of the cohort (adolescents and adults) also present a challenge for interpreting QOL outcomes. Therefore, developing and validating age-specific QOL tools for younger paediatric T1D populations is strongly encouraged.

CONCLUSION

In conclusion the QOLSID has an acceptable validity and reliability when used for Iraqi T1D patients.

Authorship Contribution: EMM conceived the study design, conduct the statistical analysis, and guided the overall project. He also reviewed and revised the initial draft prepared by NKM and oversaw the clinical data collection. NKM drafted the manuscript and conducted the initial data collection from patients, with supervision from HAA. HAA facilitated patients recruitment and supervised the clinical data collection, ensuring data quality and adherence to protocol.

Potential Conflicts of Interest: None

Competing Interest: None

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