



Research Article

Validity and Reliability of Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS) in Type 1 Diabetic Patients

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Abstract

Background: Assessing medication adherence is crucial for patients with type 1 diabetes (T1DM), as it is a primary obstacle to achieving optimal glycemic control in this population. However, none of the currently available tools to assess medication adherence are specific to Iraqi patients with T1DM. **Objective:** To assess the reliability and validity of the Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS) among Iraqi patients with T1DM. **Methods:** This cross-sectional study was conducted from January 29 to May 29, 2025, at the Faiha Specialized Diabetes, Endocrine, and Metabolism Center in Basrah, Iraq. It involved 100 Iraqi T1D patients aged ≥ 12 years diagnosed for at least 12 months and on stable treatment for at least 3 months. Participants completed a paper-based IADMAS questionnaire at baseline. Reliability was assessed using Cronbach's alpha. For test-retest reliability, 24 participants completed the questionnaire again after two weeks, and their scores were correlated using Spearman's rho. Concurrent validity was examined by comparing IADMAS scores with HbA1c levels. **Results:** The internal consistency of IADMAS, assessed using Cronbach's alpha (0.217). It can be slightly elevated to 0.266 if item 4 is removed. Regarding the test-retest results, the correlation for the total IADMAS scores was 0.458 ($p=0.024$). By inspecting individual items within IADMAS, two items showed significant differences between test and retest values. There was a non-significant association between IADMAS score and HbA1c (Spearman's $\rho = -0.087$, $p=0.391$). **Conclusions:** IADMAS has poor validity and reliability and hence it is not suitable to assess medication adherence among T1DM patients.

Keywords: IADMAS, Iraq, Reliability, Type 1 diabetes, Validity.

صلاحية وموثوقية مقياس الالتزام بالأدوية المضادة لمرض السكري العراقي (IADMAS) في مرضى السكري من النوع الأول

الخلاصة

يعد تقييم الالتزام بالأدوية أمراً بالغ الأهمية لمرضى السكري من النوع الأول (T1DM)، لأنه عتبة أساسية أمام تحقيق التحكم الأمثل في نسبة السكر في الدم في هذه الفئة. ومع ذلك، لا توجد أي من الأدوات المتاحة حالياً لتقييم الالتزام بالأدوية خاصة بالمرضى العراقيين المصابين بـ T1DM. **الهدف:** تقييم موثوقية وصحة مقياس الالتزام بالأدوية المضادة لمرض السكري العراقي (IADMAS) بين المرضى العراقيين المصابين بـ T1DM. **الطرائق:** أجريت هذه الدراسة المقطعية في الفترة من 29 يناير إلى 29 مايو 2025، في مركز الفحساء المتخصص للسكري والغدد الصماء والتمثيل الغذائي في البصرة، العراق. وشمل 100 مريض عراقي من مرض T1DM الذين تتراوح أعمارهم 12 عاماً فما فوق والذين تم تشخيصهم لمدة 12 شهراً على الأقل وتلقوا علاجاً مستقراً لمدة 3 أشهر على الأقل. أكمل المشاركون استبيان IADMAS الورقي عند خط الأساس. تم تقييم الموثوقية باستخدام ألفا كرونباخ. من أجل موثوقية الاختبار وإعادة الاختبار، أكمل 24 مشاركاً الاستبيان مرة أخرى بعد أسبوعين، وتم ربط درجاتهم باستخدام Spearman's rho. تم فحص الصلاحية المتزامنة من خلال مقارنة درجات IADMAS مع مستويات HbA1c. **النتائج:** تم تقييم الاتساق الداخلي لـ IADMAS باستخدام ألفا كرونباخ (0.217). إزالة البند 4 يرفعه إلى 0.266. فيما يتعلق بنتائج إعادة الاختبار، كان الارتباط بين إجمالي درجات IADMAS 0.458 ($p=0.024$). من خلال فحص العناصر الفردية داخل IADMAS، أظهر عنصران اختلافات ذات دلالة إحصائية بين قيم الاختبار وإعادة الاختبار. كان هناك ارتباط غير ذي دلالة إحصائية بين درجة IADMAS و HbA1c (سبيرمان $\rho = -0.087$ ، $p=0.391$). **الاستنتاجات:** IADMAS لديه صلاحية وموثوقية ضعيفة وبالتالي فهو غير مناسب لتقييم الالتزام بالدواء بين مرضى T1DM.

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INTRODUCTION

Diabetes mellitus (DM) is a major chronic illness with substantial morbidity and mortality [1]. This metabolic disease is linked to chronic hyperglycemia and requires lifelong care to maintain glycemic control and minimize complications [2,3]. A key obstacle to reaching the best glycemic results is medication non-adherence [4-6]. Therefore, assessing medication adherence is essential for DM

patients. Although general self-reported medication adherence scales such as the Morisky Medication Adherence Scale (MMAS) and Medication Adherence Report Scale (MARS) are available, disease-specific validated tools are preferable for accurate assessment of medication adherence [7,8]. Additionally, the most effective tool should be culturally appropriate to ensure its relevance and reliability [9]. A validated and trustworthy tool for assessing medication adherence among Iraqi DM

patients—the Iraqi Anti-Diabetic Medication Adherence Scale (IADMAS)—was already present [10]; however, it was validated specifically among patients with type 2 DM [10]. It is important to note that there are significant differences between type 1 and type 2 DM. These differences include, first, the necessity of insulin therapy in T1DM due to absolute insulin deficiency [11]. Second, T1DM requires complex daily self-care routines to maintain optimal glycemic control, such as carbohydrate counting, frequent blood glucose monitoring, and insulin dose adjustments [12,13]. Furthermore, T1DM predominantly occurs among children and adolescents, which can further hinder adherence to treatment due to psychosocial challenges associated with the disease [14]. These T1DM-specific adherence barriers and behaviors may not be sufficiently captured by a scale that has been validated for type 2 diabetes, which could lead to inaccurate results and compromise the scale's clinical usefulness for this population. Consequently, directly adopting IADMAS to assess adherence among T1DM patients without verifying its validity and reliability in this population is neither logical nor acceptable. Therefore, the purpose of this study is to assess the validity and reliability of the IADMAS among Iraqi people with type 1 DM and hence evaluate its clinical usefulness in identifying the level of medication adherence and adherence obstacles particular to this group.

METHODS

Study design and setting

The current study was a cross-sectional one involving Iraqi patients with a verified diagnosis of T1D who were attending the Faiha Specialized Diabetes, Endocrine, and Metabolism Center at Al-Faiha Teaching Hospital, Basrah, Iraq. The study was continued from the 29th of January 2025 to the 29th of May 2025.

Study sample and participants

Based on the "rule of thumb" for psychometric validation—which recommends a minimum of 10 participants per item [15]—an 8-item scale like IADMAS would require at least 80 participants. However, since the minimum acceptable sample size for cross-sectional studies is generally considered to be 100 [16], the target sample size for this study was set at 100 participants.

Inclusion and exclusion criteria

Patients with a confirmed diagnosis of T1D for at least 12 months, aged 12 years or older, and who had been on the same treatment and dose for at least 3 months, were deemed eligible for participation in the current study. Meanwhile, patients with acute illness, pregnant women, and those with physical or mental disabilities were excluded. All eligible patients were informed about the study objective, emphasizing that

participation was voluntary and that their decision would not impact the healthcare they receive. Only patients who consented verbally to participate were included in this study and were asked to complete the IADMAS questionnaire [10]. All participants who continued with the same treatment (same daily dose and dosage form of insulin) were asked to return after two weeks to complete the IADMAS again. However, only 24 patients return for follow-up, which is expected due to the high dropout rate among Iraqi patients [17].

Data collection

All participants were given a paper based IADMAS [Appendix A] to fill in. Meanwhile, participants with limited education or poor eyesight were assisted by the researcher in completing the IADMAS. Only participants who came back to retest completed the questionnaire twice. Glycated hemoglobin (HbA1c) levels were measured for all patients only at the beginning of the study, using the HPLC method with the Variant 11 (Bio-Rad, USA) instrument.

Ethical considerations

This study was approved by the research ethics committee at the College of Pharmacy, University of Baghdad (certificate number: RECAUBCP56202406R) in accordance with the ethical standards of the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS/WHO) and the principles outlined in the Belmont Report.

Statistical analysis

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 17. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were shown as frequencies and percentages. The Shapiro-Wilk test was used to assess the normality of data distribution. The internal consistency of the scale was evaluated using Cronbach's alpha, with a score above 0.7 and a corrected item-total correlation exceeding 0.3, indicating good reliability [18-20]. Test-retest reliability was measured using Spearman's rho correlation. Correlation strength was categorized as follows: correlation coefficients between 0.41 and 0.60 denoting good reliability, between 0.61 and 0.80 indicating very good reliability, and between 0.81 and 1.0 representing excellent reliability [21]. A p-value less than 0.05 was considered indicative of statistically significant differences.

RESULTS

The mean age of the participating patients was 23.05 ± 9.34 years, and the majority (56%) were males. Participants had DM for a mean duration of 9.14 ± 6.57 years. Most included patients (94%) used traditional insulin types (short-acting and NPH

insulin). Most (83%) of participants had diabetic complications. Further clinical and demographic data are presented in Table 1.

Table 1: Demographic characteristics of study participants

Parameter	Value
Age (year)	23.05±9.34
Gender	
Male	56(56)
Female	44(44)
Duration of DM (year)	9.14±6.57
Treatment	
Regular insulin and NPH insulin	94(94)
Mixtard insulin	4(4)
Novorapid and lantus	1(1.0)
Novorapid and Insulitard	1(1.0)
Education	
Illiteracy	2(2)
Primary	18(18)
Secondary	66(66)
Diploma	2(2)
College	11(11)
Higher education	1.0(1.0)
Diabetic complication	
Absent	17(17)
Present	83(83)
Neuropathy	77(77)
Retinopathy	40(40)
Hypertension	2(2)
HbA1c%	9.74±2.28
HbA1c rank	
Poor control (< 7)	11(11)
Good control (≥7)	89(89)

Values were expressed as frequency, percentage, and mean±SD.

The internal consistency of IADMAS, assessed using Cronbach's alpha, was found to be 0.217. It can be slightly elevated to 0.266 if item 4 is removed. The corrected item-total correlations for the whole scale items were less than 0.3 (Table 2).

Table 2: Internal consistency of IADMAS

Parameter	Corrected Item Total Correlation	Cronbach's Alpha if Item Deleted
Q1	0.115	0.179
Q2	0.229	0.117
Q3	0.024	0.225
Q4	-0.069	0.266
Q5	0.061	0.209
Q6	0.112	0.172
Q7	0.153	0.138
Q8	0.031	0.235

Regarding the test-retest results, the correlation for the total IADMAS scores was 0.458 ($p = 0.024$). By inspecting the individual items within the IADMAS, two items showed significant differences between the test and retest values ($p > 0.05$), as shown in Table 3.

Table 3: The reliability of IADMAS after re-testing

Parameter	Z score	p-value
Q1	-1.090	0.276
Q2	-1.585	0.113
Q3	-2.684	0.007
Q4	-1.430	0.153
Q5	-0.405	0.686
Q6	-0.321	0.748
Q7	-0.299	0.765
Q8	-2.299	0.021
Total score correlation	0.458	0.024

There was a non-significant association between IADMAS score and HbA1c (Spearman's $\rho = -0.087$, $p = 0.391$). Additionally, the non-significant

correlation was evident among patients in all age groups (adolescents and adults) (Table 4).

Table 4: Association of IADMAS with HbA1c (Concurrent validity)

Parameter	Correlation coefficient	p-value
All included patients (n=100)	-0.087	0.391
Adults (≥18 years) (n=66)	-0.137	0.273
Adolescents (12-19 years) (n= 43)	0.074	0.639

DISCUSSION

Although IADMAS was used to assess medication adherence in a recent study among Iraqi T1DM, its reliability and validity among such a group of patients was not assessed before its usage [22]. Indeed, the present study is the first one that assessed the internal reliability and construct validity of the IADMAS among individuals with T1DM; for instance, the conducted psychometric analysis raises significant concerns regarding the validity and reliability of IADMAS in this population. The results of the current study showed that the calculated Cronbach's α value is much lower (0.217) than the generally recommended cutoff point of 0.7 [23]. Meanwhile, even by excluding item number 4, the Cronbach's alpha can increase slightly but without reaching the target value. Moreover, all scale items had corrected item-total correlations of less than the most acceptable value of 0.3, which indicates a negligible correlation of these items with the total scale score [24]. Regarding test-retest reliability, the correlation coefficient (r) for total IADMAS after retesting was 0.458, indicating a modest level of stability over time. Moreover, significant differences between test and retest values for two individual items (Q3 and Q8) were observed. This result highlights inadequate stability of IADMAS among T1DM patients. By considering these results, it can be concluded that the reliability of IADMAS among T1DM patients is poor. This contrasts with the good reliability reported for the original IADMAS when used to assess medication adherence among T2DM patients [10]. The discrepancy may be partly due to item 8, which assesses the impact of purchasing medication on adherence. This item may not be applicable to Iraqi T1DM patients, as insulin—being a life-saving medication—is typically provided free of charge through public diabetic centers and hospitals in Iraq [25]. Consequently, economic barriers that influence adherence in T2DM patients are less relevant for T1DM patients in this context. Additionally, differences between T1DM and T2DM patients—such as treatment type and age—may further contribute to the discrepancy in IADMAS reliability [11-14]. Furthermore, the lack of reliability observed in type 1 diabetes is not surprising, as the Morisky Medication Adherence Scale—one of the most widely used tools for assessing medication adherence—has demonstrated variable reliability across different diseases and languages [26]. The results of this study showed a non-significant correlation between IADMAS scores and HbA1c levels across the entire cohort, a finding

that was consistent across both age groups: adolescents and adults. This lack of association is probably because IADMAS places a strong emphasis on taking medications as prescribed but overlooks critical processes involved in adjusting insulin doses based on carbohydrate intake, exercise, and blood glucose levels, which are essential for achieving glycemic control in T1DM patients [27]. Regardless of the reason for the lack of association between IADMAS scores and HbA1c, this finding suggests poor criterion validity of the IADMAS among T1DM patients.

Study limitations

The current study was limited by its small sample size. Additionally, for some participants, completing the questionnaire with the help and supervision of the researcher may lead to biased results due to social desirability, which is commonly observed during interviews with Iraqi patients [28]. Therefore, further research with a larger sample is necessary to confirm or refute these findings.

Conclusion

The current version of the IADMAS lacks evidence of concurrent validity against HbA1c and exhibits inadequate reliability (internal consistency and test-retest stability) in patients with T1DM. Without significant revision, its use for clinical or research purposes is prohibited by these basic psychometric limitations.

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Conflict of interests

The authors declared no conflict of interest.

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Data sharing statement

Supplementary data can be shared with the corresponding author upon reasonable request.

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