



Associated factors to insulin adherence in type 1 diabetes in Tehran and Karaj, Iran

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Abstract

Purpose Type 1 diabetes mellitus (T1DM) is a chronic metabolic disorder, and its prevalence and incidence are increasing globally. Insulin therapy is the basis of T1DM management that can prevent numerous complications. Identifying and resolving the factors involved in patients' non-adherence can reduce complications, mortality, and economic burden.

Methods In this cross-sectional study, a sample of patients with T1DM were included from Alborz and Tehran cities of Iran in 2020. Patients filled the questionnaires consisting of sociodemographic and diabetes characteristics, weight and height measurements, 8-item Morisky Medication Adherence Scale (MMAS), and barriers to insulin therapy. Patients with < six scores of MMAS were considered to have low adherence, while ≥ 6 scores showed moderate/high adherence. Data were analyzed using SPSS, and a P-value of less than 0.05 was considered statistically significant.

Results 189 patients with T1DM with a mean ($\pm$ SD) age of 17.95 ($\pm$ 10.98) years were enrolled in the study, and 73.5% of patients had moderate/high adherence to insulin therapy. Younger age and owning insurance were significantly associated with being classified in the higher adherence group. The barriers that were significantly associated with non-adherence were forgetting to buy, physician inaccessibility, cost, exhaustion from the long-term injection, forgetfulness, injection site reaction, and rebellion against parents in the < 20 years age group. The main barriers in ≥ 20 years age group were forgetting to buy and insufficient injection instruction.

Conclusion The identified barriers to insulin injection would be helpful for policymakers and clinicians to increase insulin adherence among patients with T1DM.

Keywords Type 1 diabetes Mellitus · T1DM · Adherence · Insulin

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Introduction

Type 1 diabetes mellitus (T1DM) is caused by immune-associated destruction of pancreatic β -cells [1]. In the majority of western countries, more than 90% of diabetes in children or adolescents is T1DM [2]. According to the 10th edition of the international diabetes federation (IDF) diabetes atlas, the worldwide prevalence and annual incidence of T1DM are estimated to be 651,700 and 108,300 children under 15 years. The highest incidence rates are observed in North Europe and many countries in the Middle East and North Africa [3]. The rise in the prevalence of T1DM is associated with higher psychological, medical, and financial burdens [4].

The basis of diabetic care is insulin therapy to achieve optimal glycemic control, which leads to the prevention of micro and macro-vascular complications of T1DM [5].

Various factors, including the chronic nature of the disease, fear of the side effects, painful injection, and the cost of insulin, lead to patients' non-adherence to insulin therapy, which is associated with poor glycemic control and a higher risk of complications [6].

According to the World Health Organization (WHO) report in 2003, adherence to treatment for T1DM consists of adherence to self-monitoring of glucose, insulin, diet, physical activity, and other self-care measures [7]. Regarding the adherence to insulin therapy, in a multicenter study in Brazil, the evaluation of insulin adherence by adapted 4-item Morisky Medication Scale (MMAS) questionnaire in patients with T1DM showed that 42.2% and 48.0% of the patients reported moderate and minimal adherence to their insulin regimen, respectively [8]. In another study published in 2014, 63.4% and 14.3% of patients with T1DM in Iran had medium and low adherence to insulin regimens, respectively, based on the 8-item MMAS questionnaire [6]. A study conducted by Karishma *et al.* on 4,768 patients with T1DM in the United States showed that 19% of patients missed a meal insulin dose at least once per week [9]. Despite the importance of insulin adherence in diabetes care, the studies published on this matter are variable and differ by geographical region.

Identification and resolution of insulin adherence barriers would benefit glycemic control and quality of life, prevent complications, and reduce mortality. The present study evaluates insulin adherence and its associated factors in a large number of patients with T1DM.

Methods

In the present cross-sectional study, the study population consisted of patients with T1DM. The patients enrolled in the study were selected using a weighted stratified systematic random sampling method, proportional to the size of patients with T1DM referred to the Diabetes Clinic of the Imam Ali Hospital of Alborz and patients with T1DM of the GABRIC database registry who lived either in Alborz or Tehran during 2020.

Due to the COVID-19 pandemic and fewer in-person visits, the questionnaires were filled virtually. The study was reviewed and approved by the ethical committee of Alborz University of Medical Sciences (Code No: IR.ABZUMS.REC.1399.281). Before sending the questionnaires to the patients or their guardians, they were informed of the study's aims and procedure. The questionnaires were sent if they consented to enrollment in the study and the patients were not currently admitted to the hospital. In patients younger than ten years old, the guardians would fill out the questionnaire with their child.

The questionnaire.

The questionnaire consisted of five parts: sociodemographic characteristics (age, gender, education, job, parents' education and job, home, car and computer ownership, insurance, average income), diabetes characteristics (duration of diabetes and injection device), measurements (weight and height), 8-item MMAS [10], and a questionnaire of possible barriers to insulin therapy.

MMAS questionnaire initially evaluated the medication adherence in patients with hypertension; however, currently, it is used for many chronic conditions, including chronic heart failure, malignant neoplasms, DM, and acute coronary syndrome [11]. Several studies assessed the insulin adherence in patients with type 2 DM (T2DM) receiving insulin treatment by MMAS questionnaire and proved the questionnaire's internal consistency [12–15]. The Persian version of 8-item MMAS was previously validated in patients with T2DM, including patients who receive insulin [16]. Moreover, the MMAS questionnaire was used in patients with T1DM in multiple studies to evaluate insulin adherence [6, 8, 17–20].

As for the interpretation of MMAS, if the patients' scores were less than 6, they were considered to have low adherence, while with scores of 6 and more, they were considered to have moderate/high adherence [10].

The validity and reliability of the present questionnaire were previously determined in the Farsaei *et al.* study with a Cronbach's alpha coefficient of 0.82 [6]. The questionnaire of barriers and MMAS are provided as **Supplementary Material**.

Statistical analysis.

Data were analyzed using SPSS version 26.0 (SPSS Inc., IBM Company), and a P-value of less than 0.05 was considered statistically significant. Data are demonstrated as frequency and percentage for categorical variables and mean ($\pm$ SD) or median (IQR) for quantitative variables. The association between level of adherence and continuous variables was evaluated by Mann-Whitney U-test for non-parametric variables and independent sample T-test for parametric variables. The Pearson's Chi-square test assessed the association between categorical variables. For controlling the false discovery rate, P-values of barriers to insulin therapy variables associated with insulin adherence were adjusted by the Benjamini-Hochberg method [21]. The crude odds ratio (OR) was determined using a logistic regression test to establish the association between demographic and diabetes characteristics and insulin adherence. A multiple logistic regression model was fitted to data to adjust for confounding factors. All variables with P-value < 0.2 in the univariate analysis were presented to the multiple models using the stepwise method. The results of logistic regression analysis are presented by OR and 95% confidence interval (CI).

Table 1 The association between sociodemographic and diabetes characteristics and insulin adherence

Sociodemographic and Diabetes Characteristics *		Total	Low Adherence	Moderate / High Adherence	P-value
Age, Year **		18.0 (11.0)	21.5 (10.9)	16.7 (10.8)	0.007
Age Group	< 20 years	132	27 (20.5)	105 (79.5)	0.004
	≥ 20 years	57	23 (40.4)	34 (59.6)	
Sex; N (%)	Male	83	18 (21.7)	65 (78.3)	0.188
	Female	106	32 (30.2)	74 (69.8)	
Weight Disorders +	Underweight	37	8 (21.6)	29 (78.4)	0.578
	Normal Weight	105	32 (30.5)	73 (69.5)	
	Overweight	37	8 (21.6)	29 (78.4)	
	Obese	10	2 (20.0)	8 (80.0)	
Insurance Owner		170	40 (23.5)	130 (76.5)	0.006
Additional Insurance Owner		63	18 (28.8)	45 (71.4)	0.641
Socio-Economic Status	Low	63	19 (30.2)	44 (69.8)	0.387
	Moderate	64	13 (20.3)	51 (79.7)	
	High	62	18 (29.0)	44 (71.0)	
Duration of Diabetes, years ***		4.0 (7.2)	6.0 (7.2)	4.0 (7.0)	0.116
Number of Daily Injections	Twice	11	1 (9.1)	10 (90.9)	0.747
	Three times	44	13 (29.5)	31 (70.5)	
	Four times	67	18 (26.9)	49 (73.1)	
	Five time	48	13 (27.1)	35 (72.9)	
	More than five times	19	5 (26.3)	14 (73.7)	
Injection Device	Pen	169	43 (25.4)	126 (74.6)	0.360
	Syringe	20	7 (35.0)	13 (65.0)	

* Categorical variables are presented as frequency (percentage)

** Age is presented as mean (SD)

*** Diabetes duration is presented as median (IQR)

+ Weight disorders in under 20 and over 20 years olds are defined as CDC weight for age percentiles and BMI classifications adopted by the National Institutes of Health and World Health Organization, respectively

Results

Among 189 patients with T1DM, 83 individuals (43.9%) were male. The mean ($\pm$ SD) age of participants was 18.0 ($\pm$ 11.0) years, and 132 patients (69.8%) were under 20 years old. The distribution of patients regarding socioeconomic status was even. The median (IQR) duration of diabetes was 4.0 (7.17). One hundred sixty-nine patients (89.4%) used insulin pens, and the remaining used insulin syringes. None of the participants used continuous insulin infusion.

According to MMAS, 139 patients (73.5%) had moderate/high adherence to insulin therapy, while 50 patients (26.5%) had low adherence. The study patients' mean ($\pm$ SD) MMAS score was 6.22 ($\pm$ 1.37). 20.5% and 40.4% of patients younger than 20 and 20 years-old or older had low adherence, respectively.

The sociodemographic and diabetic variables association with insulin adherence is present in Table 1. The mean ($\pm$ SD) age of patients with T1DM who had low adherence was 21.5 ($\pm$ 10.9) years, which was significantly higher than 16.7 ($\pm$ 10.8) years in patients with moderate/high insulin adherence (P-value = 0.007). Moreover, the rate of patients who had insurance was significantly higher in the moderate/

high insulin adherence group (P-value = 0.006). The sex, socioeconomic status, weight disorder, and diabetic variables in patients with T1DM were not significantly associated with insulin adherence.

The associations between sociodemographic and diabetes characteristics and low insulin adherence determined by univariate logistic regression are shown in Table 2. According to the crude model, increasing age was significantly associated with low adherence (OR = 1.04, 95% CI: 1.01–1.07; P-value = 0.009). In the multiple logistic regression, age remained significant in the adjusted model (OR = 1.05, 95% CI: 1.00–1.09; P-value = 0.032).

The barriers to insulin injection that were significantly associated with low adherence include forgetting to buy, physician inaccessibility, adverse effects, cost, exhaustion from the long-term injection, embarrassment, interference with usual daily and physical activities, and forgetfulness.

The most prevalent barriers among the < 20 years age group were inaccessibility to insulin distributing pharmacies, insulin shortage, and fear of hypoglycemia. In contrast, the least prevalent barriers in the younger group include forgetting to buy, infectious disease, and polypharmacy.

Table 2 The association between independent variables and low adherence in logistic regression model

		Crude Model		Adjusted Model*	
		OR (95% CI)	P-value	OR (95% CI)	P-value
Age (year)		1.04 (1.01–1.07)	0.009	1.05 (1.00–1.09)	0.032
Female Sex		1.56 (0.80–3.04)	0.190	1.60 (0.81–3.16)	0.176
BMI (kg/m ²)		1.05 (0.99–1.12)	0.122	0.98 (0.90–1.07)	0.692
Duration of Diabetes (year)		1.02 (0.98–1.06)	0.424	-----	-----
Syringe Injection Device		1.58 (0.59–4.21)	0.363	-----	-----
Number of daily injections	2	Reference	-----	-----	-----
	> 2	3.80 (0.47–30.46)	0.209	-----	-----
Socio-Economic Status	Low	Reference	-----	-----	-----
	Moderate	0.59 (0.26–1.33)	0.204	-----	-----
	High	0.95 (0.44–2.04)	0.890	-----	-----

All p-values less than 0.2 in the univariate model were included in the multivariate model

In the ≥ 20 years age group, 82% of patients reported adverse effects as a barrier to insulin injection, followed by inaccessibility to insulin distributing pharmacies in 75% and insulin shortage in 74% of patients. The least prevalent barriers in this group of patients were inability to inject, insufficient injection instructions, and forgetting to buy.

In the < 20 years age group, patients who determined “forgetting to buy”, “physician inaccessibility”, “cost”, “exhaustion from the long-term injection”, “forgetfulness”, “injection site reaction”, or “rebellion against parents” as barriers to insulin treatment were more likely to be in the low-adherence group. People over the age of 20 that identified the barriers to insulin adherence “forgetting to buy” or “Insufficient injection instruction” were more likely to be classified as non-adherent. At the same time, patients older than 20 years who chose “the negative attitude of friends or family” and “rebellion against parents” as barriers to insulin therapy were more likely to be classified as adherent (Table 3).

Discussion

In the present study, the evaluation of 189 patients with T1DM by MMAS in Tehran and Alborz, two cities in Iran, showed that 73.5% and 26.5% of patients had moderate/high and low insulin adherence, respectively. However, in a recent study among Egyptian adolescents with T1DM, the MMAS adherence score was not associated with glycemic control [19]. Since the adherence was evaluated solely via the MMAS method in the present study and there was no other instrument to verify the reported adherence, the results should be cautiously approached, and the focus must be on the various prevalent barriers to insulin therapy among patients with T1DM.

In a study by Alves *et al.* in southeast Brazil, adherence of 158 patients with T1DM was assessed by modified MMAS, and it was observed that 63% were adherent to overall diabetes treatment [22]. In another study in Iran in 2014, patients with T1DM were evaluated by MMAS, and 85.7% of patients had intermediate to high insulin adherence [6]. Moreover, among 89 patients with insulin-dependent DM in the Tayside Scotland database, 28% of patients obtained less insulin than the prescribed dose [23].

Age as an essential factor in adherence was evaluated in the current study, and the results demonstrated that younger patients with T1DM had significantly higher adherence to insulin therapy. However, not all studies support this finding. For instance, Farsaei *et al.* showed that regarding sociodemographic characteristics in patients with T1DM, only educational status was significantly associated with insulin adherence. As opposed to the present study, no statistically significant association was found between age and insulin adherence [6]. The possible rationale behind the higher adherence of younger patients in our study could be the supervision and surveillance of families. The importance of patients’ relationships with their families and parents should be considered in treatment approaches.

Although the level of adherence did not differ among patients with different socioeconomic statuses, owning insurance was significantly associated with higher insulin adherence, and the cost was a strong barrier to insulin adherence. This observation suggests that reducing insulin costs could lead to higher insulin adherence and diabetes control which eventually results in a lower economic burden by reducing the complication rates [24, 25].

Close attention should be paid to the psychological aspects of chronic diseases. This study demonstrated that in the < 20 years age group, exhaustion from the long-term injection and rebellion against parents were associated with lower insulin adherence. To overcome these barriers, group therapy and cognitive-behavioral therapy could be beneficial [26, 27]. Furthermore, the role of parents and their

Table 3 The association between insulin injection barriers and insulin adherence

Barriers	Total			<20 years			≥20 years		
	Low Adherence, N (%)	Intermediate / High Adherence, N (%)	P-value	Low Adherence, N (%)	Intermediate / High Adherence, N (%)	P-value	Low Adherence, N (%)	Intermediate / High Adherence, N (%)	P-value
Forget to Buy	14 (28.0)	7 (5.0)	<0.001	8 (26.9)	5 (4.8)	<0.001*	6 (26.1)	2 (5.9)	0.031
Physician Inaccessibility	24 (48)	36 (25.9)	0.003	18 (66.7)	21 (20.0)	<0.001*	6 (26.1)	15 (44.1)	0.166
Adverse Effects	36 (72.0)	77 (55.4)	0.032	18 (66.7)	48 (45.7)	0.052	18 (78.3)	29 (85.3)	0.493
Cost	36 (72.0)	71 (51.1)	0.008	21 (77.8)	50 (47.6)	0.005*	15 (65.2)	21 (61.8)	0.791
Being Away from Home	22 (44.0)	47 (33.8)	0.193	10 (37.0)	28 (26.7)	0.288	12 (52.2)	19 (55.9)	0.783
Infectious Diseases	6 (12)	18 (12.9)	0.898	3 (11.1)	10 (9.5)	0.805	3 (13.0)	8 (23.5)	0.325
Dissatisfaction with Treatment Results	14 (28.0)	35 (25.2)	0.467	9 (33.3)	23 (21.9)	0.216	5 (21.7)	12 (35.3)	0.272
Negative Attitude of Friends or Family	17 (34.0)	41 (29.5)	0.520	12 (44.4)	23 (21.9)	0.018	5 (21.7)	18 (52.9)	0.018
Painful Injection	27 (54.0)	62 (44.6)	0.145	18 (66.7)	50 (47.6)	0.077	9 (36.8)	9 (39.1)	0.768
Patients Inability to Inject	7 (14.0)	22 (15.8)	0.876	11 (40.7)	28 (26.7)	0.153	0 (0.0)	1 (2.9)	0.407
Parents Inability to Inject	-	-	-	5 (18.5)	13 (12.4)	0.407	-	-	-
Concern about Complication	21 (42.0)	59 (42.4)	0.954	16 (59.3)	43 (41.0)	0.088	5 (21.7)	16 (47.1)	0.052
Exhausted from Long-term Injection	39 (78.0)	76 (54.7)	0.002	25 (92.6)	56 (53.3)	<0.001*	14 (60.9)	20 (58.8)	0.877
Embarrassment	26 (52.0)	45 (32.4)	0.014	15 (55.6)	34 (32.4)	0.026	11 (47.8)	11 (32.4)	0.239
Insulin Shortage	34 (68.0)	100 (71.9)	0.467	19 (70.4)	73 (69.5)	0.932	15 (65.2)	27 (79.4)	0.232
Inaccessibility to Insulin Distributing Pharmacies	41 (82.0)	98 (70.5)	0.169	24 (88.9)	72 (68.6)	0.034	17 (73.9)	26 (76.5)	0.826
Polypharmacy	11 (22.0)	17 (12.2)	0.079	6 (22.2)	8 (7.6)	0.028	5 (21.7)	9 (26.5)	0.684
Interference with Usual Daily Activities	23 (46.0)	33 (23.7)	0.001	10 (37.0)	20 (19.0)	0.047	13 (56.5)	13 (38.2)	0.174
Interference with Physical Activities	19 (38.0)	29 (20.9)	0.005	9 (33.3)	17 (16.2)	0.046	10 (43.5)	12 (35.3)	0.533
Interference with Meal Planning	19 (38.0)	38 (27.3)	0.195	12 (44.4)	25 (23.8)	0.033	7 (30.4)	13 (38.2)	0.545
Fear of Hypoglycemia	35 (70.0)	80 (57.6)	0.083	20 (74.1)	62 (59.0)	0.151	15 (65.2)	18 (52.9)	0.357
Forgetfulness	25 (50.0)	28 (20.1)	<0.001	15 (55.6)	21 (20.0)	<0.001*	10 (43.5)	7 (20.6)	0.064
Insufficient Injection Instructions	12 (24.0)	26 (18.7)	0.472	7 (25.9)	25 (23.8)	0.819	5 (21.7)	1 (2.9)	0.023
Injection Site Reactions	25 (50.0)	54 (38.8)	0.089	17 (63.0)	37 (35.2)	0.009*	8 (34.8)	17 (50.0)	0.256
Rebellion against Parents	20 (40.0)	38 (27.3)	0.090	18 (66.7)	26 (24.8)	<0.001*	2 (8.7)	12 (35.3)	0.022

* *P-values that are adjusted by Benjamini-Hochberg method and considered significant in under 20 years old group*

relationship with the patients have a significant impact on their insulin adherence [28, 29].

Inaccessibility to physicians is another barrier that was found to be significantly associated with lower insulin adherence. In a study in the United States for evaluating the virtual visits with diabetes specialists instead of in-person visits, it was revealed that both types of visits were equal in controlling the HbA1c levels, and virtual visits increased the number of visits per year [30].

It is noteworthy that patients with diabetes should not be labeled as “adherent” or “non-adherent”, as these terms do not reflect the circumstances and limiting opportunities that may contribute to challenges in diabetes management [31]. The potentially negative impact of language on the management of diabetes care is becoming evident [32]. The language of healthcare professionals matters, as it can show that they care and remove biases. Curiosity toward patients’

feelings and circumstances, avoiding negative judgment, and being respectful and empathic are essential for improving communication between healthcare professionals and patients with diabetes [33]. In the present article, we aimed to decipher the factors that could lead to challenges in insulin injection to understand patients’ circumstances and try to reduce the incidence of the preventable factors by collaborative interaction with patients.

Regarding the limitations of the present study, since the patients’ laboratory data were not available, the correlation of the level of adherence with HbA1c could not be assessed. Due to the complex nature of T1DM, evaluating adherence needs to cover multi aspects of the disease. Our study lacks in this regard, and the results require further validation. In future studies, it is recommended to correlate the level of adherence with HbA1c to achieve a more objective result. Also, due to the importance of lifestyle in managing T1DM,

adherence to self-monitoring of glucose, diet, physical activity, and other self-care measures could be assessed. Moreover, since it was demonstrated that increasing age was strongly associated with low adherence, stratification of the results according to different age groups would improve the reliability of the results. However, due to the insufficient number of samples in each age group, patients were only stratified to under and over 20 years old in the present study.

Conclusion

In conclusion, various barriers of insulin injection were identified that were associated with lower adherence, among which insulin costs and psychological factors require acknowledgment. These barriers need to be considered in making policies to increase insulin adherence and reduce complications, mortality, and economic burden.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s40200-022-01105-0>.

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Declarations

Statements and declarations Competing Interests: The authors declare no conflict of interest.

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