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RESEARCH ARTICLE

Adherence to medications, self-care activity, and HbA1c status among patients with type 2 diabetes living in an urban area of Iran

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Abstract

Background Appropriate pharmacotherapy, self-care and adherence to medications are crucial to diabetes control. We aimed to study the diabetes care and glycemic control in patients with type two diabetes living in an urban area of Iran.

Methods In this cross-sectional study, patients with type 2 diabetes who attended a referral university affiliated community pharmacy and an accredited pathobiology laboratory in the 17th district of Tehran were evaluated. Data including demographics, medical and drug history were collected. Self-care activity (Diabetes Self-care Activity Measurement Scale) and medication adherence (8-item Morisky Medication Adherence scale) were also assessed. After completing the questionnaires, the patients were referred to the laboratory for Hemoglobin A1c test.

Results Three hundred forty-eight patients (60.3% females) were recruited. The mean (SD) of patients' age was 55.82 (12.72) and 75.3%of them were Illiterate or had primary education. Mean (SD) of Hemoglobin A1c levels was 8.39 (2.03) and 33% of patients had levels higher than 9%. Among study patients, 186 (53.4%) patients received monotherapy for diabetes type 2 and 200 (57.5%) patients had low adherence to medications. Physical activity, blood glucose self-monitoring and foot care were domains of self-care with the fewest practice. Re-using a pen or syringe needle more than once was reported by 83% of patients and mean (SD) time of re-using a pen needle was 9.11 (8.74).

Conclusion Poor glycemic control, low medication adherence, inadequate self-care activities, signals of inappropriate pharmacotherapy and inadequate medical visits and monitoring in the study patients highlight the importance of providing accessible and affordable health care services in the region. Moreover, educational needs of the patients should be considered especially in an area in which the majority of patients are old and illiterate and have low socioeconomic status.

Keywords Diabetes mellitus · Type 2 · Hypoglycemic agent · Medication adherence · Self-care · Hemoglobin A1c protein

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Background

Diabetes is one of the most common chronic diseases that is becoming a global epidemic due to increasing life expectancy, urbanization, increased prevalence of obesity and, in general, changing lifestyles. The adult population with diabetes in the world is estimated to increase from 135 million in 1995 to 300 million in 2025 [1]. Most of this increase occurs in developing countries. The Middle East is one of the areas with high prevalence of diabetes in the world and predicted to be ranked second in terms of the prevalence of diabetes in 2030, along with North Africa [2].

The prevalence of diabetes in Iran is steadily high and it is still rising with a 35% increase from 2005 to 2011. The latest survey in 2011 showed that 11.4% of adults in Iran are affected by diabetes (both types) [3, 4]. The prevalence of type 2 diabetes is estimated to be 24% in people over 40 years old [5] and 14.4% in adults over 60 years of age [6]. Given the high prevalence, increasing incidence, and economic burden, diabetes in Iran is a serious public health challenge.

Timely diagnosis and control of this condition play an important role in reducing the short-term and long-term complications of the disease. Appropriate pharmacotherapy, adherence to medications, proper self-care, and regular monitoring are crucial to diabetes control [7]. There are also several factors known to affect adherence to medications and self-care behaviors including cognitive impairment, side effects of drugs, lack of knowledge about disease and the role of medications, the complexity of the pharmacotherapy, and poor access to medications [8]. Therefore, providing proper education and regular health care services in these patients is of great importance.

Despite the gradual improvement of diabetes care in Iran, there are still many challenges in managing this condition [3, 9–12]. Sporadic and unpublished data showed that the diabetes care of patients with type 2 diabetes in the some regions of big cities is undesirable. Furthermore, cultural barriers, low socio-economic status and low level of literacy will increase the need of patients to be provided with accessible health care services and appropriate training [13]. In spite of relatively high prevalence of diabetes type 2 in 17th district of Tehran, diabetes care was not studied in this region of the capital city [14]. This district is located in the south west of the city and is the smallest district of capital. However, with 273,231 inhabitants and a density of 33,276/Km^2 (2016 population census), this is a region with crowded population. Socio-economic and healthcare service evaluations in this district revealed diverse community problems and major dissatisfactions [13, 15]. Therefore, we aimed to study the status of diabetes care and control in patients with type 2 diabetes in district 17th of Tehran. Our main objectives were evaluation of glycemic control, medication adherence and self-care activities in these patients. We also aimed to describe and evaluate the diabetes related medical visits and monitoring and antidiabetic pharmacotherapy.

Methods

Study design

This cross sectional study was conducted from July 2015 to December 2015 in the 17th district of Tehran, Iran. The Ethics Committee of Tehran University of Medical Sciences (Tehran, Iran), approved the study protocol.

Patients with type 2 diabetes who attended a referral university affiliated community pharmacy and an accredited pathobiology laboratory in the district of study were evaluated in terms of eligibility criteria.

Eligibility criteria

The inclusion criteria were diagnosis of type 2 diabetes and receiving diabetes medications for the last 6 months. Patients were excluded from the study in case of dementia, cognitive impairment, or schizophrenia, having a hospital admission and/or serious illness in the past month, or absence of residence in the Tehran district 17 or one of its subareas.

Study variables

In this study, data were collected on demographics, medical and drug history. In addition, to assess the patients' self-care status, Diabetes Self-care Activity Measurement Scale questionnaire [16], translated and validated in previous studies [17, 18], was used. This tool contains 11 questions about diabetes self-care behaviors in the areas of general diet, specific diet, exercise, blood glucose self-monitoring, foot care, and smoking. Answers to questions 1 through 10 were based on the number of days per week and to question 11 were as yes or no. For each of the first five domains, mean of two items is calculated for each patient. In the analysis each domain should be considered separately. The 8-item Morisky Medication Adherence scale (MMAS-8) was used to study the medication adherence status [19, 20]. This questionnaire has been translated to Farsi and administered to patients with diabetes in previous studies, and its psychometric properties have been studied [17, 21, 22]. This tool consists of 8 questions in which, 7 questions are answered as "yes" or "no", and the last question is a 5-point Likert scale. The total score of this tool is a maximum of 8, which indicates a high medication adherence. A score of less than 6 is considered as low adherence and a score of 6–7.75 is considered as moderate adherence.

After receiving verbal consent from patients, the data collection form and the questionnaires were completed by

the AJ during the interview with the patients. After completing the questionnaires, the patients were referred to the laboratory for Hemoglobin A1c (HbA1c) test. The HBA1c level in this study was measured using ion-exchange HPLC method (Bio-Rad D-10 ™).

Sample size and sampling method

The sample size was estimated to be 350, based on the population of the study area, expected prevalence of non-adherence to drug therapy (0.35) [8, 10, 17], confidence level (0.95), and estimated precision (0.05). The researcher approached patients with prescriptions of diabetes medications based on convenience sampling method.

Data management and analysis

We calculated Prescribed Daily Dose (PDD) for oral hypoglycemic agents used by our patients to compare mean PPD with the corresponding Defined Daily Dose (DDD) (World Health Organization (WHO) ATC/DDD 2017). The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults [23].

In this study, the patients were divided into two groups in terms of their glycemic control status as follows: in cases with HbA1c level less than 7 the glycemic named as good control conditions and in cases with HbA1c level 7 or more, the glycemic status was under poor control conditions [7].

Statistical analyses were performed using the SPSS software (Statistical Package for the Social Sciences, version 21.0; SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were applied to explore the data. Categorical data were analyzed using Pearson's chi-square test. Spearman rank correlation was used to evaluate correlation between scales and demographics and clinical characteristics. Furthermore, multiple linear regression was used to investigate the simultaneous effects of factors.

Availability of data and material The datasets used and/or analyses during the current study are available from the corresponding author on reasonable request.

Results

We recruited 348 patients with type 2 diabetes. The mean (SD) of the age was 55.82 (12.72), indeed 127 (36%) patients were over 60 years of age. Average diabetes duration in terms of years passed from diagnosis was 9.36 (7.81) in study patients and in 104 (29.9%) patients diabetes duration was more than 10 years. Other demographic and clinical characteristics of patients are summarized in Table 1. According to the study results, 64.1% of the subjects did not receive any diabetes education from any sources.

Table 1 Demographic and clinical characteristics of the patients

Characteristics	Frequency / mean
Sex, N (%)	
Female	127 (36.5%)
Education, N (%)	
Illiterate/no secondary education	262 (75.3)
High school/ college	52 (14.9)
Bachelor of science or above	34 (9.8)
Glycemic control, N (%)	
Good control	62 (24.5)
Poor control	191 (75.5)
Adherence (MMAS-8), N (%)	
Low adherence	200 (57.5)
High/moderate adherence	148 (42.5)
Times of re-using a needle in patients who received insulin, Mean (SD)	
Syringe needle	8.31 (11.49)
Pen needle	9.11 (8.74)
HbA1c level, Mean (SD)	8.39 (2.03)

Diabetes related medical visits and blood glucose monitoring

The mean (SD) intervals of the diabetes related medical visits was 4.1 (2.6) months. Eighty-four patients (24%) utilized general practitioner practices for follow-up, full review and / or prescription renewal. In addition, 77 patients (22%) visited physicians for the sole purpose of renewal their prescription, of which 42 (54%) referred to general practitioners. Approximately 45% of the patients went to private clinics for their latest medical visit related to diabetes.

The most commonly considered method for monitoring glucose levels by physicians in these patients was the measurement of fasting blood glucose with a frequency of 78.7%. History of HbA1c measurement was reported in only 37.1% of the subjects.

Antidiabetic pharmacotherapy

Of the patients studied, 186 (53.4%) and 144 (41.4%) patients received monotherapy and dual therapy for type 2 diabetes, respectively. The most abundant monotherapy medications were insulin preparations in 97 patients (27.9%) and metformin in 71 patients (20%). The most common dual therapy regimens in these patients were glibenclamide plus metformin in 75 patients (21.5%) and metformin plus insulin preparation in 33 patients (9.5%). In general, the most commonly used oral hypoglycemic agents were metformin (69.5%) and glibenclamide (25.6%).

Table 2 Prescribed Daily Dose (PDD) and WHO Defined Daily Dose (DDD) of selected oral hypoglycemic agents in the study patients

	DDD	PDD (Mean)	PDD/DDD ratio
Metformin (g)	2	1.5	0.75
Glibenclamide (mg)	7	10	1.4
Acarbose (g)	0.3	0.1	0.33
Repaglinide (mg)	4	2	0.5
Sitagliptin (g)	0.1	0.1	1
Pioglitazone (mg)	30	22.5	0.75

Table 2 shows PDD for selected oral hypoglycemic agents used by our patients compared to the DDD (WHO ATC/DDD 2017).

Of the 139 patients treated with insulin preparations, 72.6% of patients used pen devices and the others used vials. Patients were asked about the number of times a pen or syringe needle was used; the results of which are shown in Table 1. Eighty three percent of patients used a pen or syringe needle more than once and 58% more than 3 times.

Glycemic control

As shown in Table 1, glycemic control status was undesirable according to HbA1c results in 75.5% of patients. 84 (33%) patients had HbA1c levels of more than 9%. Thirty seven out of 84 patients (44.0%) had no history of changing their diabetes medications in the past 3 months and they were currently treated with monotherapy. In univariate regression, insulin use was the only factor affected the HbA1c (β (SE) = 0.54 (0.265) and p value = 0.04) and patients who received insulin had higher HbA1c levels.

Medication adherence

The frequency of patients with low, moderate, and high medication adherence in two groups with good and poor glycemic control is described in Table 3. In nearly two-thirds of patients with low and medium medication adherence glycemic control was poor. On the other hand, in patients with high medication adherence, 54 % had poor glycemic control. Nevertheless, statistical analysis did not show a significant association between HbA1c levels and medication adherence ($P = 0.19$).

Univariate regression results showed a significant effect of the diabetes duration and receiving both of oral agents and insulin on the Morisky score. After entering both constructs to the model, the receiving of both oral agents and insulin remained significant (β (SE) = 0.77 (0.319) and p value = 0.016). That is, in patients with same diabetes duration the Morisky score was 0.77 higher in patients received both oral agents and insulin than patients who treated with oral agents or insulin.

Self-care activities

Table 4 indicates self-care activities of the patients regarding diet, exercise, blood glucose self-monitoring and foot care. Median (IQR) number of days per week that individuals in this study devoted to general diet, special diet, exercise, blood glucose self-monitoring, and foot care were 3.5 (1.5), 4.0 (2), 0.5 (2.5), 0.5 (1.0), and 0.0 (2.37), respectively. No smoking status in the past week was reported among 91.4% of the patients.

The results of the study showed that there was a negative poor correlation between blood glucose monitoring as a component of self-care and the age of the patients ($r = -0.15$, $P = 0.006$). The gender of the patients had a significant relationship with exercise (Mean rank of 192.7 vs. 162.5 in males vs. females respectively, $P = 0.004$). Smoking was reported more in men than women (17% vs. 3%, $P = 0.000$).

Discussion

Available studies have shown that about half of the diabetic patients in Iran have poorly controlled glycemic status [3]. In our study, 75.5% of patients had an undesirable glycemic status and 33% of them had HbA1c levels above 9%. Similar results were reported in previous studies in Iran [24]. Frequency of patients with HbA1c levels more than 9% was reported to be

Table 3 Medication adherence and glycemic control

		Medication adherence (MMAS-8)[a]			Total
		High N (%)	Medium N (%)	Low N (%)	
Glycemic control (HbA1C)	Poor control	111 (78.2)	74 (74)	6 (54.5)	191
	Good control	31 (21.8)	26(26)	5(45.5)	62
Total		142	100	11	253

Pearson Chi-Square = 3.27, p value = 0.19

[a] Permission to use the MMAS scales is required. Reproduction and distribution of the MMAS is protected by US copyright laws. A license agreement to use the scale is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095–1772, dmorisky@gmail.com

Table 4 Description of patients' self-care activities

Self-care domain	Items	Self- care activity frequency (%)					Day(s) per week for each domain, Median (IQR)
		Never	Less than half of a week	Half of a week	Almost daily	Daily	
General diet	Q1	1.4	19.6	45.1	32.7	1.1	3.5 (1.5)
	Q2	0.9	16.9	57.2	24.1	0.9	
Specific diet	Q3	5.5	43.1	31.0	20.4	0.0	4 (2)
	Q4	3.4	16.1	45.1	28.1	7.2	
Exercise	Q5	6.3	9.4	13.2	26.4	44.5	0.5 (2.5)
	Q6	3.7	5.8	10.3	17.8	62.4	
Self- monitoring of blood glucose	Q7	3.7	3.1	10.9	33.6	48.6	0.5 (1)
	Q8	2.0	1.4	6.3	10.1	80.2	
Foot care	Q9	1.7	5.4	12.1	26.4	54.3	0.0 (2.37)
	Q10	1.1	7.1	14.1	20.6	56.9	

In this table, daily means every day of the week, almost daily means 5 or 6 days a week, half of a week means 3 or 4 days a week, less than half of a week means 1 or 2 days a week, and never means zero day a week

58.5% in the first National Surveillance for Non-communicable Diseases Risk Factors in 2005 [4, 9].

Pharmacotherapy is the core of the diabetes management. Considering the treatment regimens, medications used, and PDD, diabetes pharmacotherapy in our study patients seemed to be inappropriate. In this study, despite the poor glycemic control in about 75% of the patients, for more than half of them monotherapy was considered. In addition, 9.6% of the patients with HbA1c levels higher than 9% were treated with monotherapy and they did not mention the history of changing diabetes medication in the last 3 months. However, according to the American Diabetes Association guideline, monotherapy in patients with HbA1c levels higher than 9% is not acceptable [7].

About 40% of the study patients were treated with insulin preparations alone or in combination with oral hypoglycemic medications. The study of the use of diabetes medications in Iran has shown that the share of insulin from the total medications used for diabetes is only 17%, which is approximately half of the share of insulin consumption in developed countries [3, 12]. More common insulin use in the present study should be interpreted with consideration of the study setting; because it was the main pharmacy in the district that provided insulin preparations and had online access to insurance company approval systems.

The daily dosage of most of the oral hypoglycemic agents in this study was lower than the DDD. Evaluating appropriateness of the dosing merely based on the comparisons between PDD and DDD might be unacceptable. A national study in Sweden also showed that the average PDD of some oral hypoglycemic agents was lower than the corresponding DDD [25]. Researchers of the mentioned study found that this observation is more due to the discrepancy of prescribed, dispensed and consumed medication rather than inappropriate use [25]. In addition, for most medications, DDD cannot be considered as the basis for the recommended dosage. However, despite the limitations mentioned for DDD, given that metformin is the main drug for treating type 2 diabetes and its DDD is well-matched with the recommended doses, the lower mean PDD of metformin than DDD in our patients can be indicative of sub-optimal pharmacotherapy. This observation is consistent with the study patients' glycemic control. In spite of reported affordability of the essential diabetes medications in Iran [12], 45.5% of the study patients reported difficulties in paying for their medications.

Medication adherence is another important factor in achieving diabetes therapeutic goals in addition to appropriate pharmacotherapy. In our study, less than half of the patients had acceptable adherence to their diabetes medications. However, according to the results of a review study, adherence to diabetes medications in Iran was reported from 62.8 to 86.3% [8]. Due to the lack of clear definition and considering specific assessment tools for medication adherence in the studies, the results cannot be compared with the findings of our study. In studies using MMAS-8 to assess adherence to diabetes medications in patients with type 2 diabetes in Iran, low adherence has been observed in 41–93.6% of subjects [17, 22].

In contrast to studies that found a relationship between medication adherence and glycemic control in diabetic patients [26–31], our study could not show significant relation. Similarly, in the study by Ghanei Gheshlagh R. et al., there was no significant relationship between medication adherence based on MMAS-8 and HbA1c levels [22]. In fact, blood glucose in diabetic patients is controlled with a combination of appropriate pharmacotherapy, medication adherence, and self-care. In cases where the patient has an acceptable adherence to medication, but the pharmacotherapy is inappropriate, it is unlikely that the blood glucose level reaches the desired goals.

On the other hand, adherence was better in patients who received both oral agents and insulin. It was in contrary to studies that mentioned complexity of treatment regimen as a negative factor on medication adherence [32]. Surprisingly, in

a study in Spain the lowest compliance was in patients taking insulin plus an oral hypoglycemic agent [33].

Self-care activities were also inadequate in the study patients. Other small studies in different urban and rural areas in Iran have shown similar results [17, 18, 34]. Studies have shown that psychosocial and demographic factors as well as knowledge and awareness of individuals can affect their self-care behaviors [18]. In addition, education and perceived barriers were predictors of self-care behaviors in Iranian patients with type 2 diabetes [18]. Training for diabetic patients is necessary to improve the knowledge, skills, and abilities necessary for self-care, as recommended by national and international guidelines [7, 35]. Meanwhile, about 65% of the patients studied did not mention a history of training in this area. In addition, considering that more than 75% of the patients were illiterate or had primary education, consideration of special educational needs in these patients is necessary in order to improve self-care behaviors.

The intervals of the diabetes related medical visits and the frequency of patients referring only for prescription renewal indicate that studied patients could not benefit from proper medical care. Studies showed that there was not enough human resources in the country in response to the prevalence of diabetes and the need for endocrinologists [3]. In our study, 24% of patients referred merely to general practitioners and did not receive specialized medical care for diabetes. In addition, in spite of the special socioeconomic situation of people in this district of Tehran, the last place of medical visit was private clinics for 44% of the patients. Therefore, provision of available and affordable medical care facilities in the region will help improve the timely and regular specialized physician visits for the patients. In the national survey on diabetes care conducted about a decade ago in Iran, HbA1c measurement at least once a year was reported in only 6.4% of the patients [9]. In our study one third of the patients reported measuring HbA1c levels.

A considerable result of our study is the high frequency of re-using a syringe or pen needle and mean times of re-use in the study patients. In a study conducted in a clinic in Shiraz, 82.1% of patients used a syringe more than once, which is similar to our study results [36]. Nevertheless, in the mentioned study, 117 syringes were used 437 times (3.7 times per syringe), which is much less than the average use of a needle in our study. In European countries, the frequency of the repeated uses of needles and the mean (standard deviation) times of re-use has been reported to be 41% and 3.3 (3.1) respectively [37] that are lower than values in our study. Informal reports have recommended that repeated use of a needle up to 3 times might not result in complications. However, about half of the patients in our study used a needle more than three times and this requires serious action to change the practice and prevent subsequent complications.

Although the results of this observation are helpful in providing a picture of diabetes care status in patients with type 2 diabetes in suburban areas of provincial capitals in Iran, study limitations should be considered in interpreting and generalizing the results. According to the sampling method and the study settings, the results may not be generalizable. In addition, because of the lack of access to accurate clinical information and medical records of the patients, judgment about the pharmacotherapy appropriateness could not be performed accurately.

Conclusion

Diabetes care and control, in terms of proper medical visits, appropriate pharmacotherapy, glycemic control and monitoring, medication adherence and self-care activities, was far from optimal situation and goals in the study patients. In addition to providing accessible and affordable facilities, educational needs of the patients should be considered especially in an area in which the majority of patients are old and illiterate and have low socioeconomic status.

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Author's contributions Amir Jafarian recruited patients, collected the data and drafted the manuscript. Amir Sarayani participated in the study conception, study design, interpretation of the results and revision of the manuscript. Kheirollah Gholami supervised the study and participated in the study conception and design. Maryam Taghizadeh-Ghehi participated in the study design, interpretation of the results and manuscript drafting and revision. Kazem Heidari and Aarefeh Jafarzadeh kohneloo designed and performed the statistical analysis and participated in the interpretation of results and manuscript revision. Donald E. Morisky participated in the study conception and design.

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Compliance with ethical standards

Ethics approval and consent to participate Research Ethics Committee of Tehran University of Medical Sciences approved this study.

Consent for publication Not applicable.

Competing interests Morisky receives honorarium for use of the MMAS. He was not involved in the data collection or evaluation analyses. The other authors have nothing to declare.

Abbreviations *ATC,* Anatomical Therapeutic Chemical; *DDD,* Defined Daily Dose; *HbA1c,* Hemoglobin A1c; *IQR,* Inter quartile Range; *MMAS-8,* 8-item Morisky Medication Adherence scale; *PDD,* Prescribed Daily Dose; *SD,* Standard Deviation; *SE,* Standard Error; *WHO,* World Health Organization

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