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Original Article

Uncontrolled glycemia and the associated factors in Iranian type 2 diabetic patients, North of Iran: Role of self-care and self-efficacy

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Abstract

Background: Hyperglycemia caused by diabetes is closely related to long-term damage in organ functional disorders. The objective of the study was to determine the prevalence of uncontrolled glycemia and its associated factors in Iranian diabetic patients.

Methods: This cross-sectional study was conducted on 496 types 2 diabetic patients in the outpatient clinic of a referral hospital center affiliated with Babol University of Medical Sciences, North of Iran. The data of fasting blood sugar (FBS) and hemoglobin A1C were extracted from recent laboratory tests. The demographic, clinical data, and comorbidity were collected. The reliable and valid scales of self-care and self-efficacy were used to collect data through face-to-face interviews with patients.

Results: About half of the participants, 241(48.6%) patients had poor glycemic control (FBS≥152 mg/dl) and a higher proportion, 382 (79.6%) patients were found based on the criterion of HbA1C≥7%. There was no significant difference in poor glycemic control between genders. The adjusted OR for risk of poor glycemic control (FBS>152mg/dl) after controlling potential confounders was 2.37 (95%CI: 1.34, 4.12) for the duration of diabetes >15 years compared to 5 years or less. The higher level of self-efficacy prevented poor glycemic control (adjusted OR=0.50, 95%CI: 0.29, 0.87). While the high level of self-care tended to protect against poor glycemic control non-significantly (adjusted OR=0.65, 95%CI: 0.41, 1.11).

Conclusion: Our findings show that majority of diabetic patients have poor glycemic control. The high level of self-care and self-efficacy substantially reduced the risk of poor glycemic control.

Keywords: Fasting blood sugar, Hemoglobin A1C, Uncontrolled diabetes, Self-care, Self-efficacy.

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Diabetes is a metabolic disorder and its main characteristic is hyperglycemia, which is due to impaired insulin secretion (1). In both developed and developing countries, diabetes has become a global epidemic in two recent decades and it is the major leading cause of death and disability in the world. According to world statistics, in 2015, 415 million adults had diabetes and it is expected to increase to 64 million people in the world in 2040 (2). The global statistics of the IDF show that the highest prevalence of diabetes is in North America (11.5%) and Africa has the lowest prevalence (3.4%) (2). In the Islamic Republic of Iran, due to the epidemic of obesity and overweight and lifestyle changes in the past two decades (3, 4), the prevalence of diabetes, especially type 2 diabetes mellitus, is rapidly increasing in Iranian adults, and the prevalence of diabetes and pre-diabetes had been reported 15.0% and 25.0% respectively among adults of 35-70 years (5). Hyperglycemia caused by diabetes is closely related to long-term damage in functional disorders of different body organs.

In general, the pathophysiology of diabetes complications is classified into two groups: microvascular (damage to blood vessels) and macrovascular (damage to arteries). As a result, diabetes in the long run leads to vision loss, end-stage kidney disease, stroke, and amputations, which are the most common complications in these patients (6). Poor glycemic control is correlated with severe diabetic complications. The results of the clinical trial of diabetic patients in Stockholm showed that the lack of control and higher-than-average glucose levels are associated with a higher risk of neuropathy and retinopathy (7). In another trial, strict glycemic control significantly reduced the risk of cardiovascular disease (8). In a prospective study in Great Britain, the risk of fatal and nonfatal myocardial infarction was reduced by 16% in comparison between the intensive treatment groups and the usual treatment group (9). But overall, the cause of death was not significantly different in the two groups. In another trial, a 15% reduction in heart attacks and a 13% reduction in mortality was observed (10). Keeping hemoglobin A1C (HbA1C) low at the limit of 6.5% led to a 10% reduction in mortality and macrovascular complications and as a result, led to a 21% reduction in nephropathy (11).

While results were inconsistent in another study and there was no significant statistical difference observed in terms of vascular events (12, 13). Therefore, the proper management of treatment with the goal of keeping blood sugar at the optimal level is of particular importance in preventing complications and early detection. According to the American Diabetes Association and standard medical care in diabetic patients in 2017, monitoring of FBS and hemoglobin A1C are used in glycemic assessment and to control diabetes. The cutoff point of FBS>=152 mg/dl is defined as poor glycemic control (14). The use of glycated hemoglobin (HbA1C) with a cutoff value of more than 7% increases the risk of diabetic complications (14, 15). The HbA1C indicates average plasma glucose over the previous 8 to 12 weeks (15). An HbA1C of 6.5 or more is recommended as the cut-off value for the diagnosis of diabetes mellitus, however, a value of less than 6.5% does not exclude diabetes diagnosed using the glucose tests (15, 16). The American Diabetes Association (ADA) recommendation of HbA1C<7% as the treatment goal for diabetes control and thus the best cut-off value for HBA1C (14). Therefore, glycemic control and proper management for prevention and treatment are the main factors in delaying and preventing diabetic complications, in particular, diabetic retinopathy that was the most common in diabetic patients (17).

Diabetes always requires self-management and self-care to prevent acute and chronic long-term complications. Various studies have shown that glycemic control and keeping it stable at the optimal level is important in preventing short-term and long-term complications of diabetes and leads to clinical and economic benefits (18-20). Evidence shows that dealing with and controlling and keeping glucose at acceptable levels are likely with different methods, which include changes in lifestyle and changes in nutritional status, physical activity, and the use of oral drugs or insulin injections. Since diabetes is a progressive disease, strengthening the management of the disease through nutritional regimens and insulin along with lifestyle changes, including physical activity, is often needed (21, 22). But unfortunately, almost half of the diabetic patients do not achieve the HbA1c target of more than 7% (23).

Self-efficacy is defined as the patient's belief and confidence in the ability to perform goal-oriented behavior in the presence of barriers (24). Patients' self-efficacy has been shown to contribute to glycemic control through self-care practices (25, 26). However, in the relationship between self-efficacy and self-care with glycemic control, conflicting results have been reported (27, 28). For example, in a study by Beckerle et al., no significant relationship between self-efficacy and HbA1c was observed (27). On the contrary, Lin et al. reported a significant inverse relationship between self-efficacy and HbA1C (28). Meanwhile, the evidence is increasing to indicate that poor glycemic control improves by a better practice of self-care and self-efficacy (25, 26, 28-31). However, the evidence from Iranian diabetic patients is sparse. In particular, among the diabetic patients under the coverage of the secondary health care system. Since, they are in passive monitoring of their health care. In fact, there are differences in terms of delivery health care between primary health care and secondary health care systems in terms of availability of trained health care personnel. In this regard, from the public health perspective, and the evaluation of treatment management program and implementation of further interventional strategies for diabetes control, it is necessary to assess the prevalence of uncontrolled diabetes and the associated factors in Iranian diabetic patients and the data are sparse for diabetic management in the northern region of Iran, and how to maintain the blood sugar and hemoglobin A1C at the optimum level and its association with self-care and self-efficacy. Therefore, this study aimed to determine the prevalence of poor glycemic control and the role of self-care and self-efficacy in the management of type 2 diabetes mellitus.

Methods

Study design and participants: This is a cross-sectional study of 500 outpatients with type 2 diabetes who were referred to a specialized clinic affiliated with Babol University of Medical Sciences. The data were extracted from the database of the study of the quality of life of diabetic patients in 2020. The detail of sample selection and design was explained in detail elsewhere (32). In brief, adult patients with at least 1 year of diabetes diagnosis or blood sugar levels above 126 or taking blood sugar control drugs and the ages of 35-70 years were included in the study. Diabetic patients on dialysis and those with severe dementia, unable to speak in Persian, a history of using psychological drugs, and having heart and brain surgery within the past 6 months, were excluded from the study. All patients gave their written consent to participate in the study. The study protocol was approved by the Ethics Board Committee of Babol University of Medical Sciences (Ethic Code: IR.MUBABOL.HRI.REC.1401.246).

Sampling and sample size estimation: The sampling procedure was carried out sequentially from an outpatient diabetic clinic affiliated with Babol University of Medical Sciences, northern Iran. The sample size of 500 diabetic patients was calculated to estimate the prevalence of poor hyperglycemia control in diabetic patients with the presumption of 30% prevalence and a confidence level of 95% at a precision level of 0.04. In the final analysis, 4 cases with incomplete data were excluded from the study and 496 participants were entered into the analysis.

Data collection and instrument tools: Demographic and clinical data including age, gender, place of residence, education level, and history of diabetes and disease control regimen and diabetes complications including retinopathy, nephropathy/kidney failure, diabetic foot and cardiovascular diseases through a questionnaire with interview and clinical examination were collected. Kidney failure is defined as GFR<15 mL/min/1.73 m^2 or patients under treatment by dialysis (33) as well as, hypertension (HTN) was defined as SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg (34). To diagnose diabetic retinopathy (DR), the leading cause of blindness, occurs when glucose levels increase and damage the retina, which was diagnosed by an ophthalmologist using optical coherence tomography (OCT) and fundus photography to evaluate the thickness and structure of the retina, in addition to diagnosing edema, bleeding, and scarring (35, 36). Weight and height were measured by anthropometric measurements, and body mass index was calculated by dividing weight in kilograms by height in square meters. We used body mass index (BMI) as an anthropometric criterion in diagnosing overweight (BMI 25-29.9 kg/m^2) and obesity (BMI ≥ 30 kg/m^2) (37). The results of fasting blood sugar (FBS) and hemoglobin A1C were extracted from the last patient's laboratory test results. According to ADA standard of medical care in diabetes 2017, we defined the cutoff point of FBS>152 mg/dl and/or HA1C>7% as poor glycemic control (14, 15).

Diabetes management self-care scale: The standard diabetes management self-care scale (DMSCS) consists of 15 items of individual behaviors in the domains of diet, blood sugar monitoring, exercise, medication use, and foot care. This scale was originally developed and validated by Toobert et al. (38). We implemented this scale through interviews with patients. It includes five subscales: diet (4 items), exercise (2 items), blood sugar monitoring (2 items), foot care (3 items), and medication use (4 items). This questionnaire measures each item on a Likert scale from 0 to 7 within the past 7 days (none (0=none, 7=all days of week). Thus, the range of total scores of patients' self-care behaviors was from 0 to 105. Didarloo et al. confirmed the validity and reliability of the Persian version of this questionnaire and reported the internal consistency coefficient of Cronbach's alpha for this questionnaire as 0.74 (39).

Diabetes management self-efficacy scale: The diabetes management self-efficacy scale (DMSES) contains 19 items that measure the belief in the ability of diabetes self-care activities. This scale was adopted in 1999 by Van der Bijil et al. (40). The items of this scale were recorded on an 11-point Likert scale from 0 to 10 using a visual scale. This questionnaire includes five subscales: ability in healthy nutritional habits and weight control (10 items), ability to have sufficient exercise (2 items), ability in blood sugar monitoring (3 items), ability in foot care (1 item), and medication use (3 items). The range of total scores of patients' self-efficacy was from 0 to 190. The validity and reliability of the Persian version of this questionnaire had been were reported and the internal consistency coefficient of Cronbach's alpha for this scale was 0.74 (41).

Statistical analysis: Data analysis was performed by SPSS software Version 18. Descriptive statistics indicators were presented by mean±SD for qualitative data and frequency and percentage for categorical data. In bivariate analysis, a two-sample t-test for quantitative variables or a chi-square test for categorical data was carried out to determine the relationship between the factors with poor glycemic control. Univariate and multivariate logistic regression models were used to determine the factors associated with poor glycemic control (FBS>152 or HA1C>7%). The self-efficacy and self-care scores were classified into three categories: low, medium, and high. The odds ratio and its 95% confidence

interval (CI) of each level compared to the baseline category in the risk of uncontrolled diabetes (poor glycemic control) was estimated in both univariate (unadjusted odds ratio) and multivariate models (adjusted odds ratio). Using this regression model, the role of self-care and self-care variables as well as demographic variables in the odds of uncontrolled diabetes was tested and the p-value of the statistical test was considered significant if the p-value was less than 0.05.

Results

Characteristics of participants and prevalence: The mean age of participants was 55.9 ±9.6 years and the mean of FBS and HbA1C were 167.3±64.2 mg/dl and 8.6±1.7% respectively. Over half of the participants, 264 (53.2%) patients were in the age group of 40-59 years. The majority of the patients (75.8%) were women and about 74.4% were overweight/obese. A significantly higher proportion of overweight and obesity was observed in females than in males (P=0.001). A high proportion of patients were married (91.1%) and a few subjects were single (1.2%) and widow or divorced (7.7%).

In the most of patients (61.6%), the duration of diabetes was 10 years or less and their level of education was almost at primary level or illiterate (57.6%), and a significantly lower level of education was observed in women than men (P=0.001). The most complications of diabetes were kidney failure (23.0%), heart failure (38.7%), diabetic foot (50.2%), and retinopathy (59.1%). The most common comorbidity was hyperlipidemia (84.1%), history of heart disease (45.6%), and HTN (55.8%). About half of the participants (48.6%) had poor glycemic control based on the FBS>152 mg/dl cut-point and a higher proportion (79.6%) was found as poor glycemic control based on the criterion of HbA1C>7%. There was no significant difference was observed between genders in terms of poor glycemic control (table 1).

Table 1. Demographic and clinical characteristics of participants according to gender

Characteristics		Male (n = 120) n (%)	Female (n = 376) n (%)	Total n (%)	P-value
Age group	< 40 y	4 (3.33)	36 (9.57)	40 (8. 06)	0.03
	40 – 59	60 (50.00)	204 (54.25)	264 (53.22)	
	≥ 60	56 (46.67)	136 (36.17)	192 (38.71)	
Residence area	Unban	44 (36.67)	223 (59.31)	267 (53.83)	0.001
	Rural	76 (63.33)	153 (40.69)	229 (46.17)	
BMI status (kg/m^2)	< 18.5	1 (0.83)	2 (0.53)	3 (0.60)	0.001
	18.5 – 24.9	45 (37.50)	79 (21.01)	124 (25.00)	
	25 – 29.9	57 (47.50)	171 (45.48	228 (45.96)	
	≥ 30	17 (14.17)	124 (32.97)	141 (28.43)	
Marital status	Single	1 (0.83)	5 (1.33)	6 (1.21)	0.004
	Married	119 (99.17)	333 (88.56)	452 (91.13)	
	Widow	- (-)	37 (9.84)	37 (7.46)	
	Divorced	- (-)	1 (0.26)	1 (0.20)	
Duration of diabetes	≤ 5 y	30 (25.00)	124 (32.98)	154 (31.04)	0.11
	6 – 10	47(39.17)	105 (27.92)	152 (30.64)	
	11 – 15	19 (15.83)	69 (18.35)	88 (17.74)	
	>15	24 (20.00)	78 (20.74)	102 (20.56)	
Heart Disease	No	71 (59.17)	233 (61.97)	304 (61.29)	0.58
	Yes	49 (40.83)	143 (38.03)	192 (38.71)	

Characteristics		Male (n = 120) n (%)	Female (n = 376) n (%)	Total n (%)	P-value
Kidney Disease	**No**	80 (66.67)	302 (80.32)	382 (78.02)	0.002
	Yes	40 (33.33)	74 (19.7)	114 (22.98)	
How to control diabetes	**Pill**	69 (57.50)	210 (55.9)	279 (56.25)	0.93
	Insulin	24 (20.00)	76 (19.68)	100 (20.16)	
	Diet	1 (0.83)	6 (1.59)	7 (1.41)	
	Pill + insulin	26 (21.67)	84 (22.34)	110 (22.18)	
Diabetic foot	**No**	67 (55.83)	180 (47.87)	247(49.80)	0.13
	Yes	53 (44.17)	196 (52.13)	249 (50.20)	
Hyperlipidemia	**No**	21 (17.50)	58 (15.42)	79 (15.93)	0.59
	Yes	99 (82.50)	318 (84.57)	417 (84.07)	
HD	**No**	66 (55.00)	204 (54.25)	270 (54.43)	0.88
	Yes	54 (45.00)	172 (45.75)	226 (45.57)	
HTN	**No**	56 (46.67)	163 (43.35)	219 (44.15)	0.52
	Yes	64 (53.33)	213 (56.65)	277 (55.85)	
FBS	**Controlled (< 152 mg/dl)**	60 (50.00)	195 (51.86)	255 (51.41)	0.72
	Poor Controlled (≥ 152 mg/dl)	60 (50.00)	181 (48.14)	241 (48.59)	
HbA_1C	**Controlled< 7%**	22 (18.80)	76 (20.94)	98 (20.42)	0.62
	Poor control ≥ 7%	95 (81.20)	287 (79.06)	382 (79.58)	

BMI: Body mass index; HD: Heart disease: HTN: Hypertension; FBS: Fasting blood sugar; HbA1C: Hemoglobin A1C.

Associated factors based on FBS criterion: Table 2 shows that about half of the participants had low levels of self-care with no significant difference in the level of self-care between poor glycemic control (FBS=>152) and acceptable levels of FBS (FBS<152). In addition, roughly half of the subjects had also a low level of self-efficacy, and a significant difference of lower proportion of poor glycemic control was found among the high level of self-efficacy versus low level (39.3% vs 56.5%, P=0.008). Table 2 also presented the unadjusted OR and its 95% CI both in univariate and multivariate analysis using a logistic regression model.

A higher risk of poor glycemic control was found in patients with a duration of diabetes of greater than 5 years. More specifically, the adjusted OR after controlling potential confounders was 2.37 (95%CI: 1.34, 4.12) for a duration of >15 years compared to 5 years or less. The higher level of self-efficacy appeared to prevent poor glycemic control significantly (the adjusted OR=0.50, 95%CI: (0.29, 0.87). While the high level of self-care tended to be protective against poor glycemic control (Adjusted OR=0.65, 95%CI: 0.41, 1.11) but it was not achieved at a statistically significant level (P=0.58). In addition, the effect of gender, age group, and education level was not statistically significant in both univariate and multivariate analyses.

Associated factors based on HbA1C criterion: Similarly, Table 3 shows the unadjusted and adjusted OR of patients' characteristics on the risk of uncontrolled diabetes based on the HbA1C>7% cut-point that was defined as poor glycemic control. Similar to the results of Table 2, a significant dose-response relationship was found between the duration of diabetes and the odds of poor glycemic control. With a long history of diabetes of >15 years, the adjusted OR was 3.38 (95%CI: 1.58, 7.25, P=0.002). While a relatively high effect size of a protective effect of a high level of self-efficacy (OR=0.63, 95%CI: 0.32, 1.24) was found but it was not achieved a statistically significant level (P=0.18).

Table 2. The prevalence of poor glycemic control and the unadjusted and adjusted OR (95% CI) of affecting factors on the risk of poor glycemic control based on FBS ≥ 152 mg/dl criterion.

Characteristics		FBS (mg/dl)		Unadjusted OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
		< 152	≥ 152				
Sex					0.72		0.31
	Female	195 (51.86)	181 (48.14)	1 (ref)	-	1 (ref)	-
	Male	60 (50.00)	60 (50.00)	1.08 (0.71, 1.62)	0.72	1.11(0.71, 1.75)	0.31
Age group					0.48		0.23
	< 40 y	22 (55.00)	18 (45.00)	1 (ref)	-	1 (ref)	-
	40 – 59	129 (48.86)	135 (51.14)	1.28 (0.65, 2.49)	0.47	0.95 (0.47, 1.94)	0.08
	≥ 60	104 (54.17)	88 (45.83)	1.03 (0.52, 2.05)	0.92	0.68 (0.32, 1.45)	0.31
Self-care					0.25		0.58
	Low	62 (45.59)	74 (54.41)	1 (ref)	-	1 (ref)	-
	Moderate	125 (52.74)	112 (47.26)	0.75 (0.49, 1.15)	0.18	0.79 (0.51, 1.23)	0.30
	High	68 (55.28)	55 (44.72)	0.68 (0.41, 1.11)	0.68	0.88 (0.52, 1.49)	0.63
Self-efficacy					0.03		0.04
	Low	54 (43.55)	70 (56.45)	1 (ref)	-	1 (ref)	-
	Moderate	127 (50.80)	123 (49.20)	0.75 (0.48, 1.15)	0.18	0.72 (0.46, 1.14)	0.16
	High	74 (60.65)	48 (39.35)	0.50 (0.30, 0.83)	0.008	0.50 (0.29, 0.87)	0.01
Education level					0.75		0.98
	≤ high school	183 (50.97)	176 (49.03)	1 (ref)	-	1 (ref)	-
	>high school	72 (52.55)	65 (47.35)	0.94 (0.63, 1.39)	0.75	1.006 (0.64, 1.57)	0.98
Duration of diabetes					0.009		0.006
	≤ 5 y	96 (62.34)	58 (37.66)	1 (ref)	-	1 (ref)	-
	6 – 10	68 (44.74)	84 (55.26)	2.05 (1.29, 3.23)	0.002	2.08 (1.29, 3.62)	0.003
	11 – 15	45 (51.14)	43 (48.86)	1.58 (0.93, 2.68)	0.09	1.66 (0.96, 2.87)	0.07
	>15	46 (45.09)	56 (54.91)	2.01 (1.21, 3.35)	0.007	2.37 (1.34, 4.12)	0.002

FBS: Fasting blood sugar; OR: Odds ratio; CI: Confidence interval

Table 3. The prevalence of poor glycemic control, the unadjusted and adjusted OR (95% CI) of affecting factors on the risk of poor glycemic control based on HbA1C ≥ 7% criterion

Characteristics		HBA1 C		Unadjusted OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
		< 7% n (%)	≥ 7% n (%)				
Sex					0.62		0.77
	Female	76 (20.94)	287 (79.06)	1 (ref)	-	1 (ref)	-
	Male	22 (18.80)	95 (81.20)	1.14 (0.67, 1.94)	0.62	1.09 (0.61, 1.94)	0.77
Age group					0.29		0.37
	< 40 y	7 (17.50)	33 (82.50)	1 (ref)	-	1 (ref)	-
	40 – 59	59 (23.14)	196 (76.86)	0.71 (0.30, 1.67)	0.43	0.55 (0.22, 1.38)	0.20
	≥ 60	32 (17.20)	153 (82.80)	1.01 (0.41, 2.49)	0.98	0.68 (0.26, 1.80)	0.44

Characteristics		HBA1 C		Unadjusted OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
		< 7% n (%)	≥ 7% n (%)				
Self – care					0.62		0.39
	Low	25 (19.08)	106 (80.92)	1 (ref)	-	1 (ref)	-
	Moderate	51 (22.27)	178 (77.73)	0.82 (0.48, 1.41)	0.48	0.86 (0.49, 1.51)	0.60
	High	22 (18.33)	98 (81.67)	1.05 (0.56, 1.98)	0.88	1.30 (0.65, 2.59)	0.46
Self-efficacy					0.47		0.38
	Low	23 (19.17)	97 (80.83)	1 (ref)	-	1 (ref)	-
	Moderate	46 (19.09)	195 (80.91)	1.01 (0.58, 1.75)	0.98	0.86 (0.48, 1.54)	0.61
	High	29 (24.37)	90 (75.67)	0.74 (0.40, 1.36)	0.33	0.63 (0.32, 1.24)	0.18
Education level					0.87		0.77
	≤ high school	70 (20.23)	276 (79.77)	1 (ref)	-	1 (ref)	-
	>high school	28 (20.89)	106 (79.11)	0.96 (0.59, 1.57)	0.96	1.09 (0.62, 1.89)	0.77
Duration of diabetes					0.01		0.007
	≤ 5 y	42 (28.38)	106 (71.62)	1 (ref)	-	1 (ref)	-
	6 – 10	31 (21.09)	116 (78.91)	1.48 (0.87, 2.53)	0.15	1.66 (0.95, 2.90)	0.07
	11 – 15	14 (15.73)	75 (84.27)	2.07 (1.05, 4.05)	0.03	2.25 (1.13, 4.50)	0.02
	>15	11 (11.22)	87 (88.78)	3.13 (1.52, 6.45)	0.002	3.38 (1.58, 7.25)	0.002

Discussion

Our findings show the majority of diabetic patients have poor glycemic control and its prevalence was estimated as 79.6% based on criteria of HbA1C>7%. The high level of self-efficacy appeared to be significant and it negatively associated with poor glycemic control. While the high level of self-care tended to decline the proportion of uncontrolled diabetes up to 40% which may be interesting clinically but this was not achieved to be significant statistically. In addition, the prevalence of uncontrolled diabetes was higher in patients with a higher duration of diabetes.

The finding of the current study showed that over three-quarters of the study, population suffered from uncontrolled fasting blood glucose. In comparison with other studies, Moradi et al. reported that about 66% of Iranian diabetic patients were uncontrolled glycemia based on HbA1C>7% criterion (42). Similar to our findings, the prevalence of uncontrolled glycemia in Kuwait (43), Malaysia (44), Thailand (45), and Saudi Arabia (46) were 66%, 74%, 65%, and 76% respectively. The consistency of findings perhaps is due to the similarity of health behaviors and culture. In other reports from Iranian diabetic patients, the proportion of uncontrolled diabetes ranged from 50% to 75% (47, 48). The variation of uncontrolled glycemia in different regions may be partly explained by the different criteria and the cut-off point used to define it. For example, in our findings, we used both FBS>152 mg/dl and HbA1C>7% but the findings of uncontrolled diabetes were 48% and 79.6% respectively and we observed a moderate correlation (r=0.65, P=0.001) between FBS and HbA1C. The HbA1C has shown the average of FBS in the recent period of last month which is more popular than FBS alone. However, the proportion of uncontrolled diabetes was much lower in European countries. Several studies from European countries reported that 25%-42% of patients with type 2 diabetes had poor blood glucose control (49). In comparing the results of the present study with developing and developed countries, the reason for the variation in the prevalence of uncontrolled diabetes may be attributed to the level of education, culture, healthy food behaviors and availability of health care

resources, and type of insurance coverage. For example, in European countries, either national health insurance companies or health care systems cover all costs of diabetic management and patients do not afford their health care.

The findings of the current study demonstrate that self-efficacy is negatively associated with poor glycemic control by reducing the odds of poor glycemic control by up to 50%. These results can be explained by the confident characteristics of patients with high self-efficacy and their belief and ability to monitor their FBS and regulate their medication intake. This finding is in accordance with other studies conducted in Saudi Arabia (31), Malaysia (30), and Thai (25). This result highlights in promotion of health literacy, self-care, and self-efficacy through a systematic educational program for diabetic patients along with pharmaceutical therapeutic management.

Our results showed that the duration of the history of diabetes was a strong predictor of poor glycemic control in both criteria used as FBS>152 mg/dl and HA1C>7%. In our findings, the association of the duration of diabetes with poor glycemic control in accordance with other studies in developing countries (45, 46). This shows that the chronic condition and long-term duration of diabetes are more troublesome to manage patients in developing countries. Thus, the screening program of FBS monitoring in the high-risk groups helps to diagnose patients at an earlier stage and thus to manage them earlier which would be more efficient for diabetes control by changing lifestyles and diets and appropriate therapeutic management.

In the current study, we did not observe a significant difference in uncontrolled diabetes with gender, age, and education level. Our results are in contrast with other reports that a high level of education was found to prevent poor glycemic control and improve health behaviors (50). In other report, poor glycemic control was more likely in older people and those who had less than 12 years of education, and their results indicated that a higher level of education and a greater level of self-monitoring blood sugar is helpful in controlling of diabetes (50). Moreover, the results of current study in relation to age and gender with poor glycemic control, are in line with those reported in diabetic patients in a national survey of Iran (42). The effect of age and gender on diabetic control is inconsistent in other studies (42, 45, 46). The female gender may have poorer glycemic control than male (45) because of a high prevalence of obesity/overweight, low education level, and also the low level of physical activity. On the other hand, females may be concerned about their health status because of their health consciousness and thus more exposure to their health check-ups. Thus, they have a higher chance to detect their diabetes earlier. In addition, we did not find a significant association between education level and poor glycemic control. A similar finding has been observed in another study in Saudi Arabia (46). However, patients with a high level of education might have a better performance in diet adherence and awareness of diabetes complications.

Furthermore, our results show the high prevalence of hyperlipidemia (84%), diabetic foot (50.2%) HTN (55.8%), HD (45.6%), and obesity/overweight (74.4%) were the most complications and comorbidities in diabetic patients, Except for kidney failure that was more prevalent in male and obesity/overweight in female, we did not observe the differences of other complications and comorbidities between sexes. The high prevalence of diabetic comorbidities may be explained by the high proportion of uncontrolled diabetes in our studies. The high proportion of comorbidities in our findings aligns with other reports of diabetic patients (51-53).

Meanwhile, in our findings, the majority of patients (56.2%) used an oral anti-diabetic agent (pill) and about one-fifth (20.16%) used insulin only and 22.4% used both pill and insulin for their diabetic control. We did not observe significant differences in poor diabetic control between different treatment groups. While in a study by Fiseha et al., the poor diabetic control decreased significantly in patients who were treated with both an oral antidiabetic agent and insulin (54). Meanwhile, we did not find differences in poor diabetic control between residence area (rural versus urban) as well as marital status. These similar results in urban and rural populations may be due to similar access to preventive care services in diabetes control as well as similar lifestyles and health preventive program between urban and rural areas. In the current study, we did not observe significant differences between married and single people in glycemic control. This may be explained by the fact that the majority of our study samples were married. The lack of a sufficient sample of unmarried people may reduce the study power of statistical testing, while in a study by Gebrie et al., the married subjects as compared to single subjects were 55% less likely to have suboptimal glycemic control (55). The intimacy of couples may result in awareness and motivation to adhere to a diabetic control program. Therefore, the diabetic control program should focus on an extensive educational intervention program to maintain a healthy lifestyle, such as healthy foods and regular daily exercise and physical activity for weight reduction to reduce the burden of diabetic comorbidity.

The cross-sectional nature of the study limits any causal interpretation of the observed association. Thus, such as interpretation of the results must be cautious. Although our

study center was a referral hospital clinic that covers a large diabetic population in different regions, however, we would be cautious in the generalization of finding across the country. While we used a reliable and valid scale to assess self-care and self-efficacy, the data were collected through self-reporting. Thus, patients may exaggerate or underreport their own state of self-efficacy and self-care. However, this misclassification is non-differential with respect to poor glycemic control. Therefore, this non-differential misclassification does not lead to an association but it may produce in diluting the actual association between self-efficacy and self-care with poor glycemic control. Moreover, the overwhelming sample of participants in the study was females. This may limit the generalization of results for males. The greater sample of females may explain the higher proportion of diabetes in females compared with males and women may have more consciousness in monitoring their glucose level and health status. Such an overwhelming sample of women also was present in other studies of Iranian diabetic patients (33).

Our findings show the majority of diabetic patients have poor glycemic control. The high duration of diabetes has significantly more risk of uncontrolled diabetes. The level of self-care and self-efficacy substantially reduced the risk of poor glycemic control. Therefore, the social interventional strategies should focus to strengthen self-efficacy along with a therapeutic regimen in diabetic management and to perform the screening program in high-risk groups to detect diabetes earlier to promote the treatment effects.

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Ethics approval: We confirm all methods were performed in accordance with the relevant guidelines and regulations. Written informed consent to participate is taken from all participants. The Ethics Committee of the Babol University of Medical Sciences and National system of ethics in biomedical research approved the present study (code IR.MUBABOL.REC.1399.193).

Conflict of interests: The authors declare that they have or conflicts of interest in this research.

Authors' contribution: ZG: Data management, analysis, critical review of manuscript. KH: Conception in design, literature review, data analysis, and manuscript drafting. NM: Conception in design, supervision in data collection, critical review of the manuscript. All authors read and approved the final version of the manuscript.

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