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Factors Associated with Poor Glycemic Control among Patients with Type 2 Diabetes Mellitus

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Original Article

Abstract

Background: *Diabetes Mellitus (DM) is a major health problem worldwide. Different factors could contribute to the poor glycemic control in diabetic patients which lead to higher morbidity and complication rates*

Objective: *To assess the rate of glycemic control and the factors associated with poor glycemic control*

Methodology: *A cross sectional study was conducted during a period of 18 months, in Hilla city, middle of Iraq, included 400 patients with proved diagnosed type 2 diabetes mellitus for more than one year duration who attended the Diabetic Center in Hilla during the study period. The laboratory investigations were done for all study group including Fasting Blood Sugar and glycated hemoglobin A1C which was used as a predictor of glycemic control*

Results: *Poor glycemic control was reported in 67% of the studied group. The main independent factors associated with poor glycemic control were insulin treatment (OR=1. 78) and irregular visits to Diabetic Center (OR=2. 20).*

Conclusions: *Poor glycemic control rate was high among the study population. Insulin treatment and irregular visits to the Diabetic Center were important factors associated with poor glycemic control .*

Keywords: *Diabetes Mellitus, Type 2, Epidemiology, Glycosylated Hemoglobin, HbA1C, Glycemic control, Associated factors.*

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1. INTRODUCTION

Diabetes mellitus (DM) is a major chronic disease that has a dramatic increase in its prevalence in the last two decades; it involves both male and female, young adults and even children (1) It is estimated that hundreds million of people having DM worldwide. The increasing prevalence of diabetes is mainly attributed to the increasing rates of overweight and obesity and the decrease in the physical activity in most societies (2). In the Middle east more than 30 million having diabetes and it is estimated to be doubled in the next two decades (3). Unfortunately, there is a change in the trend of type 2 DM where its prevalence increasing among the younger age group due to factors like obesity, sedentary lifestyle and longer life expectancy (4). It is a fact that diabetic patients are at increased risk of complications like a heart attack or stroke, eye complications, kidney failure and diabetic neuropathy (5). On the other hand the consequence of hyperglycemia by itself led to the death where the WHO estimates that deaths from diabetes will be doubled between by 2030 (6). Diabetes has a dramatic and deleterious effects on individuals and their families and large burden on the health systems due to more outpatient visits of diabetic patients, higher rate of hospitalization and need more care (7) as well as the chronic complications and their burden. In Iraq the prevalence of DM comprises almost 10.4% of the general population according to a national survey (8); therefore it is highly speculated that there will be an expected increase in the emerging diabetes complications in the coming coupling decades. There is no doubt that good glycaemic control is an important factor that can help to prevent or reduce complications, improve the outcomes and quality of life of these patients. Therefore, estimating the control rate of patients with T2DM and recognizing the factors that may associated with poor glycemic control rates are so important for health institutions and community, not only to clarify the natural history of the disease but also to point out the important steps necessary to enhance good glycemic control. There is a strong evidence that HbA1C is a good diagnostic and prognostic marker of DM and glycemic control during the last 120 days. The use of HbA1C test can avoid the problem of day to day variability of glucose values and avoids the need for person to fast, and have preceded dietary preparation; it measures the patient's average glycemic over the last 3 months (9). However, many laboratory tests are used in diagnosis; on the top of the list is fasting plasma glucose test (FPG), FPG of 126 mg/dl (7.0 mmol/L) or higher is an indication for retesting to confirm the

diagnosis, FPG of 100 – 125 mg/dL (5.6 – 6.9 mmol/L) indicates Impaired Fasting Glucose (10). Other confirmatory tests have also been introduced like Oral Glucose Tolerance Test (OGTT), Casual Plasma Glucose Measurements (10). Hemoglobin A1C also called Glycosylated hemoglobin or HbA1C is a test that indicates how are the blood glucose levels during the past two to three months. The amount bound reflects how much glucose has been in the blood during the past average 120 day lifespan of red cells (11). Complications of Diabetes are varied and mainly related to the Micro or Macro Vascular changes. Retinopathy and even blindness, nephropathy and its end stage of renal failure neuropathy, diabetic foot and amputation. Cardiovascular complications like heart attacks, strokes, and insufficiency in blood circulation (12). The ultimate goal of diabetes management is to lower blood glucose levels, because it is well established that improving glycemic control delays the onset and retards the progression of micro vascular and macro vascular complications (13). The American Association of Clinical Endocrinologists indicates that an HbA1C of 6.5% is recommended as the primary goal (14). Many organizations like Diabetic Control and Complication Trial (DCCT) and United Kingdom's Prospected Diabetes (UKPDS) are recommending HbA1C <7% (15). In Iraq studies suggested that maintenance of HbA1C < 7% are likely to minimize the risk of developing complications (10).

2. PATIENTS and METHODS

A cross sectional study conducted in Al-Hilla city during a period of 18 months from April 2022 to October 2023. We randomly selected 400 DM patients who met the inclusion criteria and agreed to participate in the study. Patients were selected from the outpatients clinics of two hospitals in Hilla; AL-Hilla Teaching Hospital and Imam Sadiq Hospital in addition to the Diabetes Center in Al-Hilla city, using sequential sampling technique, we got a total of 400 DM patients as the final study sample.

Inclusion Criteria

1. Adult Iraqi patients with proved diagnosed type 2 DM
2. Age between 30 and 65 years
3. Both genders were included
4. Disease duration more than one year since the confirmed diagnosis

Exclusion Criteria:

Diabetic patient with one or more of the following conditions was excluded

1. Type 1 DM
2. Chronic renal disease of any stage
3. Sickle cell anemia
4. Patient who did not have recent HbA1C test
5. Refuse to participate in the study
6. Did not complete the questionnaire

Sample Size and sampling technique :

An appropriate sample size was calculated using standard sample size equation for cross sectional studies (16) using the following formula:

$$N = \frac{Z^2 \times P(1-P)}{d^2}$$

Where:
N = Sample size.
Z= standard statistics for 95% confidence level
P = expected proportion.
d = absolute precision.

According to this equation with an assumption of P = 50%, the calculated sample size was 384 patients, and approximated to 400 and were sequentially selected from the two hospitals and Diabetes center. The response rate was 100% where all patients agreed to participate in the study

Data Collection

Data were collected using a pre-prepared data collection sheet (questionnaire) through direct interview with the patients. The questionnaire included demographic data of the patients (Age, Gender, Marital status, Level of education, Residence and Occupation), body mass index, family history, comorbidities and disease related variables such as duration, type of treatment, clinical visits to the specialist doctor. Necessary laboratory investigations were performed for all patients ; blood was tested for FBG, HbA1C and other investigations were performed accordingly. The results were registered and analyzed. Glycosylated Hemoglobin (Hb A1C) in the last three month was depended as a measure tool to assess the glycemic control. This test

was performed in the laboratory of the hospitals.

For purpose of our study, HbA1C test was categorized as followed (10).

• HbA1C ≥ 7 % was considered as poor controlled/uncontrolledDM.

• HbA1C < 7% was considered as good controlled DM

The weight and height of all participants were measured and Body Mass Index (BMI) was calculated

Data Management and Analysis

The data were coded and entered into the computer using Statistical Package for Social Sciences (SPSS) version 26. Statistical tests and procedures were applied according to the type of variable. Chi – squared test used for categorical variables, logistic regression analysis was performed to predict the effect of different variables. On the glycemic control rates. All statistical tests performed at a level of significance of ≤ 0.05.

3. RESULTS

The baseline demographic characteristics of the studied group showed that high proportion of patients, (64%), were older than 50 years. Females contributed to 52% of the studied group. Most patients, (89%), were married. Almost 43% of patients had primary or less level of education. Among the studied group, 71% were urban residents, 63% unemployed, 52% had positive family history, 19% smokers and 78% were overweight or obese (**Table 1**). Distribution of the disease related variables and comorbidities of the studied group revealed that 62% of the patients had a disease duration of < 6 years, 74% had regular visits to the Diabetic Center , 52% using oral anti diabetic agents. Regarding the history of comorbidities, 49% of the patients were hypertensive, 16% had coronary artery disease (CAD), 21% had hyperlipidemia, and 4.5% had other comorbidities. Regarding the management behaviors of the patients it had been found that only 32% of the patients followed a diabetic meal plan as recommended by the dietitians (healthy diet), 15% only participate in physical activity, 49% performed self-monitoring of blood glucose (SMBG) and most of the patients (90%) were good adhere to their medications, (**Table 2**). According to the levels of HbA1C, out of the 400 patients , 268 (67%) had a HbA1C ≥ 7% (poor glycemic control), on the other hand, 344 (86%) of the patients had fasting blood glucose (FBG) of ≥ 126 mg/dl. According to these findings, the rate of poor glycemic control was 67%, (**Table 3 and Figure 1**). Univariate analysis was

performed using chi-squared test and revealed that poor glycemic control was significantly associated with older age, >60 years, female gender, secondary level of education, urban residence, unemployed and higher BMI. On the other hand, poor glycemic control was significantly associated with shorter duration of diabetes of <6 years, positive family history of DM, irregular visits to the specialist physicians in the center, receiving insulin treatment, presence of comorbid hypertension, in all comparisons, (P. value < 0.05). No significant association was found with other variables, (P>0.05). However, regression analysis revealed that receiving insulin treatment (OR = 1.72, P = 0.000) and irregular visits to the diabetic Center (OR = 2.20, P = 0.018), were the important significant independent risk factors associated with increased odds of poor glycemic control, (**Table 4**).

Table 1. Demographic characteristics of the studied group (N=400)

Variables		No.	%
Age (years)	≤ 50	144	36.0
	51 - 60	156	39.0
	> 60	100	25.0
Gender	Male	192	48.0
	Female	208	52.0
Marital status*	Married	356	89.0
	Unmarried	44	11.0
Level of education	less than primary	78	19.5
	Primary	91	22.8
	Secondary	126	31.5
	University	105	26.3
Residence	Urban	284	71.0
	Rural	116	29.0
Occupation	Employed	148	37.0
	Unemployed	252	63.0
Family history of DM	Yes	208	52.0
	No	192	48.0
Smoking	Smoker	76	19.0
	Non-smoker	324	81.0
Body Mass Index	Normal	88	22.0
	Overweight	192	48.0
	Obese	120	30.0

Unmarried include single, divorced and widows

Table 2.Disease related variables and comorbidities of the studied group

Variables		No.	%
Duration of DM	< years	248	62.0
	≥ 6 years	152	38.0
Visit to physician	Irregular	104	26.0
	Regular	296	74.0
Type of diabetic medication	Oral	208	52.0
	Insulin	180	45.0
	Combined	12	3.0
Comorbidities	Hypertension	196	49.0
	CAD	64	16.0
	Hyperlipidemia	84	21.0
	Other comorbidities	18	4.5
Management behaviors	Follow recommended eating plan	128	32.0
	Participate physical activity	60	15.0
	Perform SMBG	196	49.0
	Adherence to medication		
	Good	360	90.0
	Poor	40	10.0

CAD: Coronary Artery Disease. SMBG: self-monitoring of blood glucose

Table 3. Frequency distribution and proportion of patients according to HbA1C test and Fasting Blood Sugar test

Variables		No.	%
HbA1C	≥ 7 %	268	67.0
	< 7 %	132	33.0
FBG	≥ 126 mg/dl	344	86.0
	< 126 mg/dl	56	14.0

FBG: Fasting blood glucose

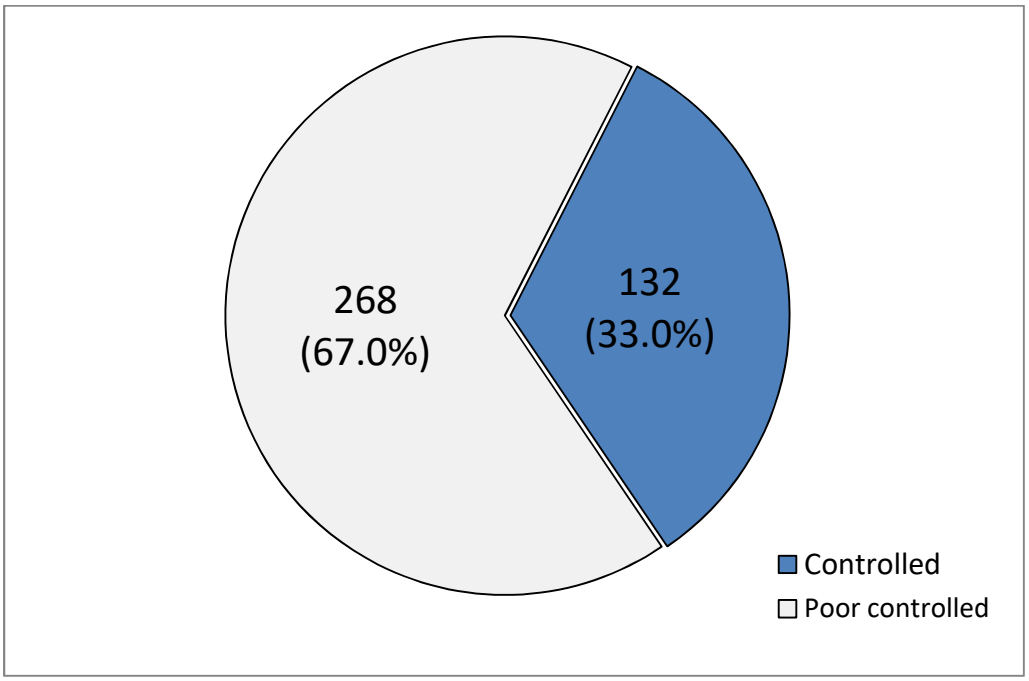

Figure 1. Rates of Glycemic control of 400 diabetic patients in Al-Hilla city.

Table 3. Results of univariate analysis for the correlation between independent factors and poor glycemic control

Independent Variable	Vs. poor glycemic control	
	Chi-square	P. value
Age (older)	10.35	0.006
Gender (female)	7.32	0.007
Marital status (married)	4.57	0.102*
Level of Education (secondary)	14.23	0.004
Residence (Urban)	25.91	<0.001
Occupation (unemployed)	8.33	0.040
Duration of Diabetes (<6 years)	15.27	<0.001
Family History of DM (positive)	7.24	0.007
Visit to Diabetic physician (irregular)	12.10	0.001
Treatment type (insulin)	14.91	0.001
Current smoking	0.626	0.429*
Body Mass Index (higher)	9.22	0.010
Hypertension (none)	5.79	0.016
CAD	2.210	0.138*
Hyperlipidemia	0.943	0.331*

*Not significant, all other variables had significant association (P. value <0.05)

Table 4. Final results of binary regression analysis for the predictors of poor glycemic control among the studied group (N=400).

Variables		OR	95% CI	P. value
Type of Diabetic Medication	*Oral agent alone	1.00	1.00	-
	Insulin alone	1.72	1.24 - 3.41	<0.001
	Combined (Oral +Insulin)	1.68	0.996 - 4.29	0.078
Regularity of Visit to Diabetic Center	*Regular	1.00	1.00	-
	Irregular	2.20	1.143 - 4.238	0.018

OR: Odds ratio, 95%CI: 95% confidence interval of OR. * reference category

4. DISCUSSION

Achieving the ideal blood glucose level is very difficult for many patients with diabetes, therefore, in the current study , the rate of optimal glycemic control with type 2 diabetes mellitus had an HbA1C less than (7%) around (33%) of the patients. Such a level of control which may be different from country to another; however the good glycemic control (HbA1C < 7%) of the patients with type 2 diabetes was reported in 58%, 49%, and 30.9% of the patients, from Pakistan (2), Colombia (17), and Malaysia (18), respectively. While the optimal glycemic control (HbA1C < 7%) of patients with type 2 diabetes in the Arab countries was (33.9%) in Jordan (19) and 27% in Saudi Arabia (20). The current study showed a statistically significant association between poor glycemic control and older age (≥ 60 years), which agreed Saudi Arabia and Malaysian studies, (21,22) On the other hand, a Meta – analysis of randomized trials conducted on 4472 patients with type 2 diabetes mellitus, showed that improving glycemic control was particularly beneficial in younger patients with shorter diabetes duration (23). The association between older age and poor glycemic control may be attributed to poor self-care among elderly, diabetic complications and the presence of other comorbid diseases, such conditions are likely to affect patients adherence to medications and could thereby have an indirect impact on glycemic control, and this supports the increasing body of literature advocating a special consideration for older adults with diabetes. The present study showed that, there was a statistically significant association between poor glycemic control and female gender, which reflected that females may have greater difficulty in achieving the glycemic control than males. This result was in agreement with previous studies

(24,25). On univariate analysis, our study showed a significant association between poor glycemic control and low level of education which similar to other studies (21,26,27). We did not find a significant association between poor glycemic control and marital status so as other study did (13). The results showed poor glycemic control was significantly associated with that patients in urban residence, occupation and shorter duration of DM (≤ 6 years); Effect of short duration of DM on glycemic control may be due to improper management, poor knowledge about the disease squeal or probably because the patients did not follow the proper diet plan or may be not performing regular physical activity. Our findings regarding these variables consistent with that reported in previous studies (28–30). We found that patients with positive family history were more liable to have a poor glycemic control which supported the finding earlier study (31). The positive family history itself may not be associated with better knowledge or perception of adequate glycemic control and the fact that patients with positive family history of diabetes tended to have a poor glycemic control and to develop diabetic complications at an earlier age. We observed that poor glycemic control was more common in patients with irregular visits to the Diabetes Center which also documented in previous studies (32,33). We found that poor glycemic control was more common in patients on insulin treatment, which was also concluded by other authors (24,34). This may be related to the fact that patients treated by insulin are more difficult to be controlled because those subjects have a more severe disease or may be due to lack of knowledge about appropriate insulin regimens and their uses, and probably due to that patients with type 2 diabetes when finally start to receive insulin they have already a more severe stage of diabetes therefore it is much more difficult to control than before. We did not find a statistically significant association between glycemic control and smoking, other investigators in previous study did not demonstrate a significant association tween glycemic control and smoking, which supported by our study (35,36). In the current study a statistically significant association was found between poor glycemic control and being overweight or obese compared to those with normal BMI. Similar findings reported in earlier studies (13,37). In the present study, a significant association was found between poor glycemic control and presence of hypertension as comorbidity with DM. No statistically significant association was found between glycemic control and CAD, similar findings also reported earlier (38,39). In contrast, a study in Saudi Arabia found a significant

correlation between the HbA1C level and severity of CAD (40). No statistically significant association between poor glycemic state (HbA1C levels) and hyperlipidemia, a similar finding was illustrated in Iran (35). Our results revealed that the patients who did not follow a diet plan (unhealthy diet) are more likely to have a poor glycemic control, many studies agreed with our finding like (13,41). Therefore most of the studies agreed with the fact that following an eating plan as recommended by dietitian or intensive nutrition therapy associated with a lower HbA1C test, indicating that food habits in our region may play a role in this poor control of blood glucose (20). Physical activity acts like a medicine. It lowers insulin resistance (insulin resistance stops sugar from getting into the muscles, which is common in type 2 diabetes, it means that insulin is not functioning well) and helps move sugar from the blood to get into the muscles (35). The present study showed that the poor glycemic control present in patients who did not perform physical activity. Our results is in agreement with systematic Review and Meta-analysis which showed that structured exercise of more than 150 minutes per week was in statistically significant association with an absolute HbA1C reduction of (0.89%) (42). Also a meta-analysis of clinical trials on selected studies showed a statistically significant correlation between HbA1C test and physical activity, (43). Regarding the SMBG, the present study has shown that, there was no statistically significant association between glycemic state (HbA1C levels) and SMBG. This association is supported by other studies from Canada and Iran (35,44), in contrast to the results of Turkish study which demonstrated that SMBG was important for the achievement of glycemic goals (45). In our study it is apparent that although patients are testing their blood glucose, they are not using this information to make proper adjustments to their therapeutic approach, due to the fact that the patients are probably not choosing the correct time to do this test (according to WHO criteria (46), as the test must be done before the meal or at bedtime). Our results showed that patients who were poorly adherent to medications were more likely to have poor glycemic control. This finding was in agreement with the results of other studies in USA (47) and Jordan (19). For patients with diabetes, adherence often means initial increases in medical costs before improved outcomes are attained, strategies aimed at simplifying treatment regimens for patients with diabetes could aid in promoting adherence and improving treatment and outcome (47). The present study has shown that, there was a highly statistically significant association between glycemic state

(HbA1C levels) and fasting blood sugar (P = 0.000), as poor glycemic control (HbA1C > 7%) was associated with high FBS. This finding is supported by many studies (48,49).

5. CONCLUSIONS

Poor glycemic control rate was high among type 2 diabetes mellitus population, contributed for 67%. Poor glycemic control was associated with most demographic and clinical factors however, logistic regression analysis, showed that Insulin treatment alone and irregular visits to Diabetic Center were the only significant independent variables associated with poor glycemic control . We recommend perform the HbA1C test at least two times a year in patients who are meeting treatment goals (and who stable glycemic control) and quarterly in patients whose therapy has changed or who are not meeting glycemic control. More intensive efforts, measures and interventions are needed especially for those patients on insulin treatment and those with low education levels. A comprehensive action should be taken to develop a public health intervention strategy to educate population and increase their awareness about the risk factors and complications of diabetes. Also we suggest conducting further large scale studies including multiple centers and larger sample size for more precise conclusions

Ethical Clearance:

Ethical issues were taken from the research ethics committee. Informed consent was obtained from each participant. Data collection was in accordance with the World Medical Association (WMA) declaration of Helsinki for the Ethical Principles for Medical Research Involving Human Subjects, 2013 and all information and privacy of participants were kept confidentially.

Conflict of interest: Authors declared none

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