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Prevalence of Glycemic Control and Factors Associated With Increasing Levels of Hba1c Among A Sample of Palestinian Patients With Type 2 Diabetes Mellitus

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ABSTRACT

Diabetes mellitus (DM) is an increasing health challenge. Control of blood glucose level, as measured by level of glycated hemoglobin (HbA1c), is used as an indicator of glycemic control and potential risk of diabetic complications. This study aimed to investigate the extent of glycemic control among type 2 diabetic patients and to determine factors associated with increasing levels of HbA1c.A total of 380 patients were interviewed using a questionnaire prepared for this cross – sectional study. The patients were recruited from a diabetic clinic in Nablus, Palestine. Clinical laboratory data and HbA1c values were obtained from medical files of the patients while demographic information were obtained through face-to-face interview. The participants had a mean ± standard deviation (SD) age of 60 ± 10 years. A total of 71 (18.7%) participants were less than 50 years of age. The participants had a mean body mass index (BMI) of 32.7± 6 Kg/m^2 with more than two thirds were considered obese with a BMI of ≥ 30 Kg/m^2. The studied patients have a mean ± SD of HbA1c of 8.3± 1.8. The median of HbA1c was 8.05 with interquartile range of (First quartile (Q1) = 6.93; Third quartile (Q3) = 9.5). The majority of studied patients (278; 73.2%) had HbA1c value above 7%. The mean ± SD healthcare index (HCI) of the studied patients was 4.29 ± 1.49. Univariate analysis showed that age ($p<0.01$), total cholesterol ($p<0.01$), low density lipoprotein (LDL) ($p<0.01$), high density lipoprotein (HDL) ($p=0.028$), HIC ($p<0.01$), and type of therapeutic regimen ($p<0.01$) were significantly correlated with HbA1c. Multivariate analysis indicated that younger age, lower HDL values, combination therapy with insulin were significantly associated with increasing levels of HbA1c.High proportion of patients recruited for this study had poor glycemic control. Younger age was associated with higher HbA1c values which necessitates urgent and immediate medical intervention at the primary healthcare level.

Keywords: Glycemic Control, Palestine, Diabetes Mellitus, Multivariate Analysis.

BACKGROUND

Diabetes mellitus (DM) is an increasing global and regional public health challenge [1-4]. It's estimated that there was about 381.8 million adults with DM worldwide in 2013 and the number is expected to increase to 55% by 2035 [2]. Diabetes mellitus affects all regions in the world. However, the prevalence of DM in the Middle East and the projections of DM for the future are prominent for the Middle East Arab region [5]. Despite the rising rates of DM in the Middle East Arab region, research activity on DM in the Arab countries is lagging behind globally and regionally when compared with neighboring non-Arab countries such as Turkey or Iran [6, 7]. In Palestine, a small area in the Middle East, research on prevalence of DM and its complications are scarce and sometimes relatively old [8, 9]. Some recently published reports on DM from Palestine discussed specific aspects of DM in certain categories of patients such as patients with schizophrenia [10, 11].

Diabetes mellitus has major complications on patient's health which could adversely affect him/her financially, and drain the governmental budget allocated for health [12, 13]. It has been shown that

good glycemic control can help patients avoid serious diabetic complications [14-17]. A trustful and commonly used indicator of glycemic control is glycated hemoglobin concentration (HbA1c) which is a presentation of blood glucose levels in the previous 2 – 3 months [18-20]. It has been suggested by the American Diabetes Association that HbA1c level less than 7 % is a good indicator of optimal glucose control and HbA1c level more than 7% as an indicator of poor glycemic control [21]. Higher levels of HbA1c were significantly associated with dyslipidemia particularly lower HDL values [22-25].

Several studies have been carried out and published about the status of glycemic control among diabetic patients in several regional countries such as Jordan, Saudi Arabia, Iran, and others [26-29]. The differences in life style, cultural habits, healthcare system, and awareness in diabetes – related health issues create differences in prevalence and type of factors associated with glycemic control among different countries. In Palestine, the government is the main provider for health services, particularly for patients with chronic diseases such as DM. The unstable political and financial situation of the Palestinian national authority is a major hindering factor for the provision of continuous high quality services to Palestinian patients. This increases the burden on patients with DM who needs continuous monitoring and follow up to achieve glycemic control. A considerable amount of literature has been published on diabetic patients in Palestine [6, 10, 30-39]. To our minds far too little attention has been paid to the prevalence of glycemic control among diabetic patients. Therefore, this cross-sectional study investigates the prevalence of glycemic control among a sample patients with type 2 DM attending a major governmental primary healthcare unit in Nablus, Palestine. Furthermore, the study will investigate the clinical and demographic factors that are significantly associated levels of HbA1c above 7%. Such study will help promote the health status of diabetic patients and decreasing the consequent economic loss due to treatment of diabetic complications if healthcare providers were aware of the prevalence of glycemic control and the health mechanisms required to optimize glycemic control among diabetic patients.

METHODS

Study design and settings

This was a cross-sectional descriptive study that involved patients with type 2 DM attending Al-Makhfia healthcare center for regular follow up. Al-Makhfia healthcare center is the largest governmental primary healthcare center in Nablus, North Palestine. The center provides health services for diabetic patients. There are more than 2000 diabetic patients registered in this center who receive regular medical follow up and get their medications dispensed at the center for minimum charges.

The study was carried out on patients who were attending the clinic and were waiting to see the physician. The followings were used as inclusion criteria for the study: patients with type 2 DM, willingness to participate in the study, physically and mentally able to provide all data required for the study, had regular follow up at Al-Makhfia diabetic clinic, and had done all laboratory tests required for study at least once during the last three months at Al-Makhfia clinic. When there were two values for any clinical laboratory test in the past three months, the mean value was calculated and used in the analysis. Exclusion criteria were the followings: type 1 diabetic patients and patients with missing HbA1c value in the past 3 months. The sample size was estimated to be 380, using Raosoft sample size calculator [40] assuming a margin of error to be 5% and a confidence level of 95%.

Two of the investigators attended the clinic daily for three consecutive months for data collection. One of the investigators approached the patients who were in the waiting area and asked for their permission to participate in the study. Patients who gave consent to participate were asked to sign a consent form in accordance with the ethical

requirements. The first investigator carried a face –to– face interview with the patients using a pre-designed questionnaire that involved questions pertaining to the demographic information, health seeking behavior, and clinical information pertaining to duration of DM, body weight, height, and blood pressure. The second investigator was in charge of examining the medical file of the patient and extraction of the clinical and laboratory information which included the level of HbA1c, lipid profile, other co-morbid diseases, and any other relevant laboratory information such as renal or liver function tests. Approval of the study by the Institutional Review Boards (IRB) and the Palestinian health authorities was obtained before the initiation of this study. Written approval was obtained from the Ministry of Health to allow the investigators to get access to the patients and their records at Al-Makhfia primary healthcare center. The data were collected in the period between September and December 2016.

Health Care Index (HCI)

In order to assess the patients' healthcare seeking behavior and management pattern, Health Care Index (HCI) was used. The HCI was based on the followings: frequency of diabetic clinic visits, number of blood pressure measurements, number of weight measurements, weather the patient did ECG, funds exam, proteinuria, and lipid profile test during the last six months. The first three variables were assessed according to the median value, if the patient had frequency of the variable above the median, then he/ she will take 1 point in the scoring system and if the frequency is less than the median, then he/she will take a zero in the scoring system. The last four variables were assessed by yes or no. If the patient performed the test at least once during the last six months, then he/she will get 1 point, if not, then he/ she will get zero points. The overall of these seven variables were summed (the highest score is seven and the least score is zero).

Regarding lipid profile results, normal values were adopted based on what the Palestinian MOH laboratory values. Total cholesterol was considered to be normal if it was less than 200 mg/ dL, LDL was normal if it was <100 mg/ dL, normal triglycerides if it was <150 mg/ dL. Regarding HDL, for males the target HDL is ≥ 40 mg/ dL, for females it should be ≥50 mg/dL.

Statistical Analysis

Statistics used in this manuscript was performed using SPSS version 21. Mean ± SD (standard deviation) and median (first quartile – third quartile) were used to present continuous data while frequency and percentage were used to present categorical data. Normality test for the HbA1c values was performed using Komogrove – Smirnove test. In this study, the HbA1c value were not normally distributed and non-parametric tests were used to perform analysis. For univariate analysis, Spearman correlation was used to test for significant correlation between HbA1c values and various continuous variables while Mann – Whitney and Kruskal Wallis were used to test for significant difference between categorical variables (e.g. gender) in HbA1c values. For multivariate analysis, linear logistic regression was used with HbA1c value as dependent variable. Only variables with significant results in univariate analysis were used in logistic analysis. Significance was set at values less than 0.05.

RESULTS

Demographic characteristics

A total of 380 patients with type 2 DM participated in the study. Females (220; 57.9%) constituted more than half of the participants. The mean age of the patients was 60±10 years with 71 (18.7%) participants were less than 50 years of age. The mean duration of DM in studied patients was 11.2 ± 8.2 years with 115 (30.3%) of studied patients had an illness duration of less than five years. The mean BMI of the participants was 32.7± 6 Kg/m^2 with more than two thirds considered obese (their BMI ≥ 30 Kg/m^2). The majority of participants were non-smokers 280 (73.7%), and had no university or college education (332; 87.4%).

Details about demographic characteristics of the study sample are shown in Table 1.

Table (1): Demographic and clinical characteristics of study patients.

Variable	Statistics	Variable	Statistics
Age (years)		**Co-morbid conditions**	
Mean ± SD	60 ± 10	Yes	150 (39.5)
Median (Q1 – Q3)	60 (53 – 67)	No	230 (60.5)
Age (years) category		**HCI score**	
<50	71 (18.7)	Mean ± SD	4.1 ± 4.2
50-59	130 (34.2)	Median (Q1 – Q3)	4 (2 – 5)
60-69	128 (33.7)		
≥ 70	51 (13.4)		
Duration (years)		**HCI score**	
Mean ± SD	11.2 ± 8.2	< 3	122 (32.1)
Median (Q1 – Q3)	10 (5 – 16)	≥ 4	258 (67.9)
Duration (years) category		**Total Cholesterol**	
<5	115 (30.3)	Mean ± SD	170 ± 45.9
5-10	105 (27.6)	Median (Q1 – Q3)	163 (137.25 – 97.75)
10-15	58 (15.3)		
≥ 15	102 (26.8)		
BMI (kg/m²) category		**Total Cholesterol (category)**	
Mean ± SD	32.7 ± 6	Normal	301 (79.2)
Median (Q1 – Q3)	31.95 (28.83 – 36.20)	Abnormal	79 (20.8)
BMI (kg/m²)		**Triglyceride**	
<25	22 (5.8)	Mean ± SD	179.7± 94.3
25-30	96 (25.3)	Median (Q1 – Q3	155 (120 – 216)
> 30	262 (68.9)		
HbA1c (%)		**Triglyceride**	
Mean ± SD	8.3 ± 1.8	Normal	180 (47.4)
Median (Q1 – Q3)	8.05 (6.93 – 9.5)	Abnormal	200 (52.6)
HbA1c (%) category		**LDL**	
< 7	102 (26.8)	Mean ± SD	85.3 ± 36.1
>7	278 (73.2)	Median (Q1 – Q3)	79 (60 - 105)
Gender		**LDL (category)**	
Male	160 (42.1)	Normal	269 (70.8)
Female	220 (57.9)	Abnormal	111 (29.2)
Tobacco		**HDL female**	
Yes	100 (26.3)	Mean ± SD	53.19 ± 13.48
No	280 (73.7)	Median (Q1 – Q3)	51 (44 – 62)
Treatment type		**HDL female**	
Not defined	7 (1.8)	Normal	113 (51.4)
Oral agent	151 (39.7)	Abnormal	107 (48.6)
Insulin	78 (20.5)		
Insulin + oral agents	144 (37.9)		
Level of education		**HDL male**	
Illiterate	50 (13.2)	Mean ± SD	46.93 ± 11.31
< high school	282 (74.2)	Median (Q1 – Q3)	45 (39 – 53)
>High school	48 (12.6)		
Hypertension		**HDL male**	
Yes	255 (67.1)	Normal	107 (66.9)
No	125 (32.9)	Abnormal	53 (33.1)

HCI: healthcare index; HDL: high density lipoprotein; LDL: low density lipoprotein
LDL, HDL, Triglycerides, and Total cholesterol are measured in mg/ dL
BMI: body mass index.

Clinical characteristics

The studied patients have a mean ± SD of HbA1c of 8.3± 1.8. The median of HbA1c was 8.05 with interquartile range of (Q1= 6.93; Q3= 9.5). The minimum recorded value of HbA1c was 4.6 and the maximum recorded value was 14.0%. The majority of studied patients (278; 73.2%) had HbA1c value above 7%. HbA1c values were not

normally distributed with a normality test *p* value less than 0.01. Clinical laboratory investigation showed that more than two thirds of the patients have hypertension (255; 67.1%) and more than one third reported having diabetic complications in the form of retinopathy and/ or cardiac complications (150; 39.5%). The mean ± SD of total cholesterol was 169.94 ± 46 mg/ dL with 79 (20.8%) of studied patients having total cholesterol above 200 mg/ dL. For triglycerides, the mean ± SD was 179.68 ± 94.32 with more than half of the studied patients (200; 52.6%) having TG above 150 mg/ dL. For LDL, the mean ± SD was 85.26 ± 36.10 mg/ dL with 111 (29.2%) patients having LDL value ≥ 100 mg/ dL. For HDL values, approximately one half of female patients (107; 48.6%) had values that are lower than recommended, while this was the case in approximately one third of the male patients (53; 33.1%). The healthcare index (HCI) of the studied patients had a mean ± SD of 4.29 ± 1.49 and a median of 4. The range of HCI values was 0 to 7 with the higher values indicating more concern about health, frequent visits to clinics, frequent weight and blood pressure measurement. A total of 122 (32.11%) patients had an HCI of ≤ 3 while the remaining 67.89% had an HCI score ≥ 4.

Univariate analysis

Demographic and clinical variables were tested for significant relation with HbA1c value. there was significant correlation between HbA1c and the following continuous variables: duration of illness (p=0.02), triglycerides (p=0.024), age (p<0.01), total cholesterol (p< 0.01), LDL (p<0.01), HDL (p=0.028), HIC (p<0.01), and type of therapeutic regimen (p<0.01). Age was significantly and negatively correlated with HbA1c value where older patients have lower HbA1c values than younger ones. For both cholesterol and LDL, there was significant positive correlation with HbA1c. For, HDL values, there was a significant negative correlation with higher HDL values were associated with lower HbA1c values. For type of therapeutic regimen, patients on oral anti-diabetic therapy had significantly lower HbA1c than those on insulin therapy, or the patients on insulin and oral anti-diabetic therapy. There was no significant difference in HbA1c value between those on insulin therapy versus those on insulin and oral anti-diabetic medications. No significant difference was found in HbA1c values and the following categorical variables: gender (p=0.17) or smoking (p=0.35), or history of hypertension (p=0.561) or presence of co-morbid conditions (p=0.21). Similarly, there was no significant correlation between HbA1c and the following continuous variables: BMI (p=0.57), diastolic blood pressure (p=0.10), and systolic blood pressure (p=0.90).(Table 2 & 3)

Table (2): Univariate analysis of demographic and clinical variables with HbA1c using Spearman correlation.

Variable	*p* value	Correlation (r)
HbA1c * Age	<0.01	-0.18
HbA1c * BMI	0.57	-0.03
HbA1c * Duration	0.02	0.12
HbA1c * Systolic BP	0.90	0.007
HbA1c * Diastolic BP	0.10	0.08
HbA1c * Cholesterol	<0.004	0.15
HbA1c * Triglyceride	0.024	0.14
HbA1c * LDL	<0.001	0.167
HbA1c * HDL	0.028	-0.11
HbA1c * HCI Score	0.006	0.14

HCI: healthcare index; HDL: high density lipoprotein; LDL: low density lipoprotein; BMI: body mass index; BP: blood pressure.

LDL, HDL, Triglycerides, and Total cholesterol are measured in mg/ dL

Table (3): Univariate analysis of categorical variables with HbA1c

variable	(HbA1c) Mean ± SD	HbA1c Median (Q1 – Q3)	*p* value*
Gender			
Male	8.42 ± 1.82	8.1 (7.2 – 9.7)	0.17
Female	8.16 ± 1.77	8 (6.8 – 9.4)	
Tobacco			
Yes	8.38 ± 1.81	8.0 (7.1 – 9.7)	0.35
No	8.23 ± 1.79	8.2 (6.9 – 9.4)	
Co-morbid conditions			
Yes			0.21
No	8.39 ± 1.75	8.2 (7.0 – 9.70)	
	8.20 ±1.82	8.0 (6.9 – 9.4)	
History of HTN			
Yes	8.23 ± 1.76	8.0 (6.9 – 9.4)	0.56
No	8.35 ± 1.87	8.1 (7.2 – 9.7)	
Therapeutic regimen			
Oral drugs	7.74 ± 1.69	7.5 (6.4 – 8.6)	< 0.001
Insulin	8.52 ± 1.81	8.4 (6.9 – 9.9)	
Oral + Insulin	8.76 ± 1.73	8.5 (7.5 – 9.9)	

HTN: hypertension
*Statistical tests used were Mann-Whitney and Kruskal Wallis test.

Multivariate analysis

Linear regression was used to find significant factors associated with increasing levels of HbA1c. The dependent variable was HbA1c value entered as a continuous variable. Independent variables were those which significant *p* values in univariate analysis and included: age, cholesterol, LDL, HDL, HCI, and type of therapeutic regimen. All independent variables were entered as continuous variables except for the type of therapeutic regimen which was used as categorical with code 1 meaning oral anti-diabetic therapy, code 2 meaning insulin therapy, and code 3 meaning insulin and oral anti-diabetic therapy. The outcome of the regression was presented in Table 4.

Table(4): Multiple linear regression analysis of association between factors and HbA1c values

Variables	Unstandardized Coefficients B	Standardized Coefficients B	*P*	95.0% Confidence Interval for B	
				Lower Bound	Upper Bound
Age Continuous (1-year units)	-0.029	-0.164	**0.002**	-0.047	-0.011
Duration of DM Continuous (1-year units)	0.002	0.007	0.895	-0.022	0.025
Therapeutic regimen					
Insulin + Oral	0.477	0.237	**0.000**	0.262	0.693
Oral	Reference				
HCI score Continuous	0.072	0.059	0.256	-0.052	.195
Total Cholesterol Continuous	0.009	0.220	0.117	-0.002	0.019
Triglycerides Continuous	-0.001	-0.069	0.366	-0.004	0.002
LDL Continuous	0.001	0.026	0.830	-0.010	0.013
HDL Continuous	-0.019	-0.139	**0.031**	-0.037	-0.002

HCI: healthcare index
HDL: high density lipoprotein
LDL: low density lipoprotein

The model indicated that factors significantly associated with increasing levels of HbA1c value were younger age, lower HDL values, and combination therapy with insulin.

DISCUSSION

This study was carried out to assess the prevalence of glycemic control and the factors that are significantly associated with increasing levels of HbA1c among a sample of Palestinian type 2 diabetic patients. The design of this study was cross sectional and therefore the results obtained in our study do not indicate causality. The major results obtained here was that the majority of studied patients had poor glycemic control with HbA1c value above 7. Furthermore, younger age, use of combination therapeutic regimen (concomitant insulin and oral hypoglycemic agents), as well as low HDL levels were main significant factors associated with increasing values of HbA1c. The absence of several patients' characteristics as significant factors associated with higher HbA1c values is in agreement with a study conducted in Netherlands among type 2 diabetic patients which concluded that finding significant predictors of poor glycemic control in primary healthcare practice is difficult [41].

Our study showed that a large proportion of diabetic patients had poor glycemic control with HbA1c value above 7. Several similar studies carried out in the Middle Eastern region came with similar conclusion where a large proportion of studied patients had poor glycemic control. A study in Jordan found that approximately 65% of diabetic patients had HbA1c value above 7 [26]. Another study in Jordan came up with lower percentage of people with poor glycemic control but the results are still considered high [42]. The HbA1c values in some Arab gulf countries is higher than that reported in Jordan and closer to the results presented in our study [43-46]. The poor glycemic control among Palestinian diabetic patients in this study could be attributed to poor medication or dietary adherence. A previous study showed that medication adherence among diabetic patients has detrimental effects on glycemic control [47]. A study in Palestine investigated the rate of medication adherence among diabetic patients and came up with the result that more than 60% of diabetic patients in Palestine had poor or moderate adherence to hypoglycemic agents which adversely affected their glycemic control [30]. Another study carried out in Palestine indicated that more than 50% of Palestinian diabetic patients had knowledge score less than 8 out of 14 when measured using Michigan diabetes knowledge test (MDKT) [37].

Advancing age has been reported by other researchers to be associated with lower HbA1c value [48, 49]. It is possible that with advancing age, patients became more aware of potential negative consequences of DM and tried to be more adherent to diet and medications to maintain a good glycemic control. Regarding complicated regimens and its association with higher HbA1c, it is expected that people with higher HbA1c level to be prescribed insulin and other glycemic control medications [50]. Our study showed that combination therapy including insulin is significantly associated with increasing HbA1c value which is an expected result given that physicians tend to prescribe combination therapy to lower HbA1c value in patients with poor glycemic control. Patients with combination therapy are usually those with deteriorated glycemic control that necessitates the use of more aggressive therapy, including insulin, to control blood glucose level to hinder the development of diabetic complications. The finding regarding the association of combination therapy with higher HbA1c level is in agreement with previous published studies which made similar conclusion [26, 41].

Univariate analysis showed significant association between HbA1c levels and dyslipidemia which is consistent with previously published reports. A study carried out in type 2 diabetic patients showed that there was a direct and significant correlation between HbA1c and various types of lipids including total cholesterol, LDL, triglycerides and HDL with inverse correlation in the case of HDL [51]. Similar finding were reported in other studies [52,

53]. In our study, low HDL values were significantly and inversely associated with HbA1c values. A recent study showed that good glycemic control is associated with increased level of HDL [54]. It is important here to clarify that the relationship between HbA1c value and HDL levels does not mean that high HDL levels causes lowering of HbA1c. It could be the opposite and that the poor glycemic control with high HbA1c is causing the abnormal levels in HDL [55].

Our study is the first to discuss the issue of glycemic control among Palestinian diabetic patients attending governmental primary healthcare units. Palestinian diabetic patients with governmental insurance might not have the optimal access to medications or healthcare needed for diabetic patients due to the financial instability of the Palestinian National Authority which affects the quality of health services offered to diabetic patients, as well as, other patients with chronic diseases. However, there is no doubt that the cross-sectional nature of our study and the sample size drawn made our conclusion to be of a pilot nature rather than a national result. Furthermore, the causality of significant factors with high HbA1c levels obtained in this study remain questionable given the cross-sectional design of the study. Finally, the sample size and the use of a single center to recruit patients are considered limiting factors in this study.

CONCLUSION

The majority of Palestinian diabetic patients attending governmental primary healthcare center had poor glycemic control with younger patients having greater risk of having higher HbA1c values. Attention should be made to patients with dyslipidemia since it is significantly associated with higher HbA1c values. More than one third of the diabetic patients were receiving combination therapy of insulin and oral hypoglycemic therapy indicative of deteriorating glycemic control.

List of abbreviations

DM, Diabetes mellitus; HbA1c, glycated hemoglobin; HDL, high density lioporotein; LDL, low density lipoprotein; TG, triglycerides; TC, total cholesterol; BMI, body mass index; IRB, Institutional Review Board; HCI, Healthcare index

DECLARATIONS

Ethics approval and consent to participate

Patients included in the study were asked to give an informed consent based on the Institutional Review Board (IRB) of An-Najah National University approval of the study.

Consent for publication

All patients agreed to the anonymous use of their clinical data for research purposes

Availability of data and materials

The raw data supporting the findings presented in the current study will be available from the corresponding author upon request

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

MS, AH, and NI collected data, performed the analyses and literature search, and drafted the manuscript. WS conceptualized and designed the study, coordinated the study and data analysis, interpreted the data, and assisted in final write-up of the manuscript. Then all read, and approved the final manuscript. Interpretation

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CONFLICT OF INTRESTS

The authors report no conflicts of interest in this manscript.

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