

HbA1c: Point of Care Testing in Control of Type-2 Diabetes Mellitus in Population of Nowshera, Pakistan

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Abstract

Background: Diabetes mellitus is a highly prevalent non-communicable disease with a further implication of the development of life-threatening diseases like cardiovascular disease and stroke.

Objective: To determine the glycosylated hemoglobin levels utility in assessing the point of care testing in the control of diabetes mellitus in the population of Nowshera in a hospital-based study.

Methodology: This was a cross-sectional study, conducted in the department of Pathology in collaboration with the Department of General Medicine, Qazi Hussain Ahmed Medical Complex, Nowshera, from 30 February 2019 to January 2020. Descriptive statistic was used for describing the variables. A Chi-square test was used for the association of HbA1c in gender groups. SPSS version 25 was used for data analysis.

Results: Out of the total 119 patients, 44 (37%) were males and 75(63%) were females. The mean age with standard deviation was 53±9.5. The Mean HbA1c with standard deviation was 10.53± 2.38. Sixty-eight (57.1%) of the patients were in the age range 46-60 years. Eighty-eight (73.9%) were poorly controlled diabetics with HbA1c of >9%. Using the chi-square test it was observed that gender has no significant impact on the severity of the disease (p= 0.38). The relative risk of female gender and for age >50years was (RR=1.11).

Conclusion: We observed that the majority of the patients had poorly controlled diabetes with HbA1c >9% which is an alarming situation. Age and gender play a very important role in the prognosis of diabetes mellitus.

Keywords: Diabetes mellitus, Glycosylated hemoglobin, Glycemic control.

Article Citation: Khan H, Shabir H, Khan MB, Zahoor S, Asif M, Khan S. HbA1c: Point of Care Testing in Control of Type-2 Diabetes Mellitus in Population of Nowshera. JSZMC 2021;12(1):17-21. DOI: <https://doi.org/10.47883/jszmc.v12i1.95>

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Introduction

Diabetes Mellitus affecting a huge population of all age groups, with alarming global prevalence irrespective of gender, ethnicity, and habitat.¹ A diabetes prevalence survey published in British Medical Journal regarding Pakistan based on HbA1c data covering 18856 eligible participants, reported the prevalence of Type 2 diabetes in 16.98% population. Pre-diabetes was also reported to be prevalent in 10.9% of the target population.¹ The prevalence in age categories was highest in age 51-60 years of age as 26% (95% CI), in class-III obese (35%), with a family history of DM (31%), and in female gender (17.8%).^{1,2} Hence the recent prevalence data suggests a higher rate of pre-diabetes in the country much higher than the previously reported studies.^{1,2} A study reported shows Pakistan ranking at 7th

position within the high burden countries worldwide and is expected to jump to position four if the condition remains unnoticed by the decision-makers.³ Glycosylated hemoglobin (HbA1c) is a standard marker that measures the blood glucose levels of the last 4-6 weeks. HbA1c measures the glycemic status and is more sensitive and specific than random or fasting readings.⁴ The higher percentage of HbA1c refers to poor glycemic control.

Available literature shows that every 1% drop in the HbA1c has a strong clinical association with a significant reduction in case fatality risk associated with diabetes mellitus.⁵ Every 1% drop in HbA1c reduces the chances of myocardial infarction by 14% and decreases the risk of cerebrovascular complications by 37%.^{6,7} The Glycosylated Hemoglobin (HbA1c), over the last two decades has

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Received: 25-06-2020

Published: 11-05-2021

become the gold standard test to monitor the glucose level in diabetics.⁸ The levels of HbA1c are directly related to the risk for complications associated with diabetes.⁹ HbA1c levels vary in gender, age categories, and ethnic groups in the healthy population. Therefore, there are recommendations that each region should establish its reference range for the HbA1c for non-diabetic, pre-diabetes, and diabetes.¹⁰

The number of tests of HbA1c is a measure of quality control of diabetes. The frequency of diabetic patients with one or more HbA1c tests per year was 91% and the same in the poorly controlled category was 27% ($p=0.05$).¹¹ Present study was therefore designed to determine the glycosylated hemoglobin levels utility in assessing the point of care testing in the control of diabetes mellitus in the population of Nowshera in a hospital-based study.

Methodology

A cross-sectional study was conducted in Pathology Department from February 2019 to January 2020. We determined the sample size of 119 using open-epi software with a margin of error at (5%), Confidence level at 95%, taking the anticipated mean of HbA1c at 6.62% from the diabetes prevalence survey of Pakistan, keeping drop out at 10% to estimate the true population.¹ Ethical approval was sought out from the Ethical Committee of the Medical Teaching Institute, Nowshera Medical College/QHAMC, Nowshera. The inclusion criteria were all known diabetic patients received in the Pathology department for HbA1c testing, irrespective of age and gender. While the exclusion criteria were all patients with co-morbidities and those who were already on insulin therapy were also excluded. Similarly, terminally ill diabetic patients or patients with cognitive disorders due to complications were also excluded from the study.

Two milliliters of blood was taken in an EDTA tube using aseptic techniques by venipuncture. HbA1c test was performed on Roche Cobas E411 Chemistry Analyzer. Calibration was done as per the instructions of the manufacturer.

Patients were grouped/categorized on the basis of HbA1c levels as per guidelines;¹ Non-diabetic, 4-5.9%, Good control Diabetes, 6-7%, Fair control diabetes, 7.1-8.9%, and Poorly controlled diabetes as >9%.

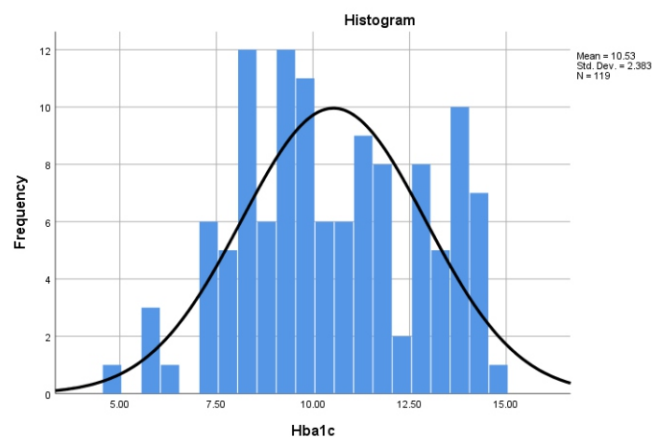
Necessary information was recorded in SPSS Version 25th designed as per the objectives of the study. Chi-square test was used for categorical variables in gender groups. Descriptive statistic was used for describing variables like age and HbA1c levels. The Odds Ratio was calculated for stratification of age and gender categories to enumerate the risk factors for poorly controlled diabetes using risk analysis statistics.

Results

Out of the total 119 patients, 44 (37%) were males and 75 (63%) were females. The age of patients was from 12 years to 75 years with a mean and standard deviation of age as 53 ± 9.5 years. The mode of age was 45 years. The mean with a standard deviation of the HbA1c was 10.53 ± 2.38 . The minimum HbA1c recorded was 4.8% with a maximum of 15% and a range of 10.2%.

The distribution of the HbA1c among diabetic patients was normally distributed. (Figure-I)

Figure-I: Distribution of HbA1c among diabetes patients.



We also applied the Kolmogorov-Smirnov test (Sample >50) to show the normality of data and observed an insignificant p-value of 0.2, representing that data is normally distributed. (Table-I)

Table-I: Tests of Normality on HbA1c Distribution

Variable	Gender	Kolmogorov-Smirnov		
		Statistic	Df	Sig.
Hba1c	Male	.097	44	.2
	Female	.116	75	.015

It was astonishing to note that 88 (73.9%) out of 119 were poorly controlled diabetics with HbA1c >9%. Similarly, 26 (21.8%) were having fairly controlled diabetes with HbA1c between 7.1 to 8.9%. Only 4 (3.4%) patients had good control of diabetes with HbA1c between 4 to 5.9% at the first appointment. (Table-II)

Table-II: Diabetes Control Categories based on HbA1c.

Diabetes Control Category	Frequency	Percent
Non-diabetic	1	0.8
Good control (4-5.9%)	4	3.4
Fair control (7.1-8.9%)	26	21.8
Poor control (>9%)	88	73.9
Total	119	100

We divided the patients into the age categories and observed that 68 (57.1%) of the patients were in the age range 46-60 years, followed by 27 (22.7%) in the age range 31-45 years, 23 (19.3%) in the age group of > 60 years, and only 1 (0.8%) in the age group 12-30 years.

We used the categorical variables (gender vs HbA1c categories) and assessed the association between the categories. Apparently, it seemed that the female gender dominated the poorly controlled diabetes category but at a 95% Confidence interval using the chi-square test this association was not statistically significant at a p-value 0.3. (Table-III)

Table-III: Association of gender with Diabetes Control

HbA1c vs Gender		Gender		Total	P-value
		Male	Female		
HbA1c Category	Non-diabetic	0	1	1	0.324
	Good control	0	4	4	
	Fair control	10	16	26	
	Poor control	34	54	88	
Total		44	75	119	

We cross-tabulated the gender with two categories of the HbA1c (HbA1c \leq 9, and HbA1c \geq 9.1) to find the Odds Ratio of gender in poor control of diabetes. It was obtained from the analysis that the female gender was a Risk factor with a value of 1.11 that is greater than 1. Then we cross-tabulated the age categories (\leq 50 years, and > 50 years of age) with two categories of the HbA1c (HbA1c \leq 9, and HbA1c \geq 9.1) to find the Odds Ratio of advancing age in poor control of diabetes. It was obtained from the analysis that age category 2 that is more than 50 years of age was a risk factor with a value of 1.01 that is greater than 1.

Discussion

Type 2 diabetes mellitus is a metabolic disorder, which is characterized by hyperglycemia has a strong association with renal, ophthalmic, and neuropathic attributed to its microvascular complications. Likewise, macrovascular complications include cardiovascular and cerebrovascular complications. Many studies have reported HbA1c as the gold standard for diabetes. The volume of HbA1c has dramatically increased over the past few decades globally, and many researchers have attempted to determine how the test should be performed and how to interpret for specific geographical areas under study.^{8,9,12} In the present study, we observed a maximum number of patients 85/119 (71.42%) were registered for the purpose of provision of free insulin in social welfare program initiated by the administration of QHAMC. The rest of the patients visited the outdoor department. The age range of patients was from 12 years to 75 years, with mean age with a standard deviation of 53 \pm 9.5 years. The mean with a standard deviation of the HbA1c was 10.53 \pm 2.38. The present study comprised mainly of diabetic patients and we aimed to determine the diabetic control using HbA1c as a tool for validation of our objectives. It was astonishing to note that 88 (73.9%) out of 119 were poorly controlled diabetics with HbA1c of > 9%. Similarly, 26 (21.8%) were having fairly controlled diabetes with HbA1c between 7.1 to 8.9%. Similar findings have been reported in a study reported from Ghana, where they reported the prevalence of diabetes as 13.6% with 86.5% of the diabetic with poorly controlled glycemic levels.¹³ We observed female gender predominance in poorly controlled diabetics. Out of the total 119 patients, 44 (37%) were males and 75 (63%) were females. Abid S et al¹⁴ from Agha Khan

University Karachi reported in a trial on the prevalence of diabetes that female gender predominance was observed in both symptomless and complicated diabetes groups. We also find our statistics consistent with Kerman Coronary Artery Disease Risk Study (KERCADRS) reports published in the International Journal of Health Policy Management, that the mean level of HbA1c in total subjects was $8.56 \pm 4.72\%$ and only 31.66% of males and 26% of females had acceptable levels of HbA1c.¹⁵ A local study reported the mean HbA1c in their target population as 9.3%, which coincides with our findings.¹⁶

We observed that 68 (57.1%) of the patients were in the age range of 46-60 years, followed by 27 (22.7%) in the age range of 31-45 years. Our findings are supported by Diabetes prevalence survey of Pakistan that was executed in MTI Hayatabad Medical complex, Department of Endocrinology, Government of Khyber Pakhtunkhwa, and department of Public Health Khyber Medical University in collaboration with the University of Manchester UK and Pakistan Endocrine Society from April 2017 to November 2017, that showed the highest prevalence in the age range 51-60 years (26.03%, $p < 0.001$).¹ The mean age was 45.23 years (SD 13.97 years) in the Diabetes prevalence survey of Pakistan that was lower than our findings of 53+9 years. We divided our patients in Hb1c categories ($HbA1c \leq 9$, and $HbA1c > 9.1$) to find the Odds Ratio of gender in poor control of diabetes. We observed that the female gender has an Odds Ratio with a value of 1.11 that is greater than 1, and almost similar results were found for age > 50 years. Our findings were supported by many authors that female gender especially in the age range 45-60 years are at high risk of diabetes with accomplished poor control.^{14-16,1,10} Diabetes has very serious implications on life expectancy. This depends on the various factors like age of the patient, gender, how soon one can receive diagnosis and treatment, and last but not least that how is he/she managed for the poorly controlled diabetes.¹⁷

Conclusion

It was concluded that the majority of the patients had poorly controlled diabetes with $HbA1c > 9\%$. Age and gender play a very important role in the prognosis of diabetes mellitus. Female gender and age more than 50 years function as risk factors of

poorly control of diabetes mellitus in our setup, so it may affect mean and median survival time in poorly controlled diabetes. Therefore the physician should pay more attention to diabetic patients with age more than 50 years, female gender in addition to the duration of disease for more than 10 years, those are more at risk to develop complications and co-morbidities to meet the worst outcome with the end of lives.

Authors Contribution: **HK:** Conception of work, design of work and revising. **MBK:** Acquisition and analysis of data and drafting. **SH:** Conception, interpretation of data and drafting. **SZ:** Conception, acquisition and analysis of data and drafting. **MA & SK:** Conception, interpretation of data and drafting. All authors critically revised and approve its final version.

Conflict of Interest: Author has declared no conflict of interest.

Sources of Funding: The source of funding was self.

Disclaimer: None

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