

TREND OF GLYCATED HEMOGLOBIN TESTING IN DIABETIC PATIENTS: TO ASSESS COMPLIANCE WITH CLINICAL PRACTICE GUIDELINES

Sameena Ghayur*, Hina Tariq**

*Shifa College of Medicine, Islamabad, **Shifa International Hospital, Islamabad

ABSTRACT

Objective: To determine appropriate use of glycated hemoglobin (HbA1c) testing in accordance with current recommended guidelines.

Study Design: Descriptive study.

Place and Duration of Study: Chemical Pathology Department Shifa International Hospital, Islamabad from Oct 2011 to Oct 2012.

Material and Methods: We randomly selected 170 known diabetic patients' data from our Laboratory Information System (LIS) who were retrospectively analyzed for HbA1c to check for intervals and test frequency for each patient in one year. Patients with follow-up for at least one year at Shifa International Hospital, Islamabad and having their routine investigations in our chemical pathology laboratory were included. The concentrations of HbA1c for all the specimens were measured immunoturbidimetrically using a microparticle agglutination inhibition method. Four guidelines namely World Health Organization (WHO), American Diabetic Association (ADA), Canadian Diabetic Association (CDA) and National Institute for Health and Clinical Excellence (NICE) about HbA1c testing were utilized for data interpretation. All tests ordered within a 2 months period or more than 6 months following the previous order were labeled as inappropriate.

Results: Only 35.8% of the patients were being properly monitored as per guidelines. Out of 64% patients who were inappropriately monitored, 12.9% had repeat orders within 2 months while 51.1% of patients were being monitored at longer interval against recommended guidelines.

Conclusions: Glycated hemoglobin is a useful tool to objectively assess the prior glycemic control of patients with type 1 and type 2 diabetes. The study highlights that in large proportion of diabetic patients, HbA1c is not utilized properly as a tool to assess the risk of diabetic complications but in a small proportion is also tested unnecessarily which adds to avoidable health expenditure.

Keywords: Diabetes, Glycated hemoglobin.

INTRODUCTION

Diabetes mellitus is a chronic debilitating illness that necessitates continuous medical care and awareness of upcoming recommendations by recognized associations. This is needed to prevent acute complications and to reduce the risk of long-term complications¹.

Asians have a strong ethnic and genetic predisposition for diabetes and develop diabetes at a younger age with a lower body mass index and waist circumference as compared to the Western population. These countries make up more than 60% of the World's diabetic population as the prevalence of diabetes is increasing in these

countries². World Health Organization predicts national income losses of US \$ 557.7 billion and US \$ 236.6 billion of China and India, respectively, for diabetes and cardiovascular disease between 2005 and 2015³.

Glycated hemoglobin has been used over 40 years in clinical practice for monitoring glucose control in diabetic patients. Its role has been recognized in assessing the risk of microvascular and macrovascular complications⁴. HbA1c component constitutes about 60-80% of total glycated hemoglobin⁵. Various studies advocate that a patient having well-controlled diabetes will have 50% of their HbA1c formed in the month prior to sampling, 25% in the month before that, and the remaining 25% over 2-4 months. This explains HbA1c use for estimation of glycemic

Correspondence: Dr Sameena Ghayur, Associate Prof. of Pathology, Shifa College of Medicine, Islamabad.

Email: sameena.ghayur@yahoo.com

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control⁴. Every 1% decrease in HbA1c level reduces the risk by 21%,⁵ for any end point related complications of diabetes^{6,7}.

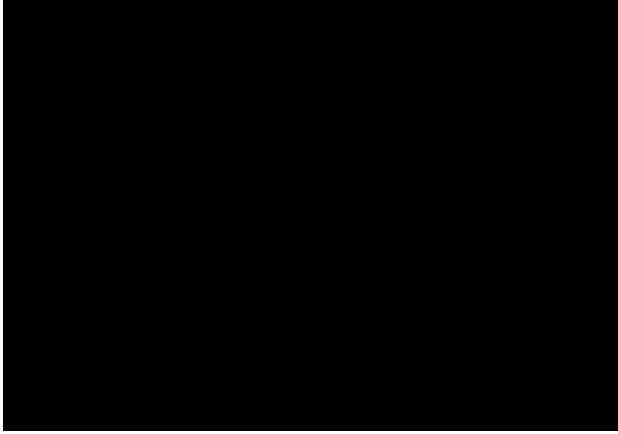


Figure-1: Trend of HbA1c.

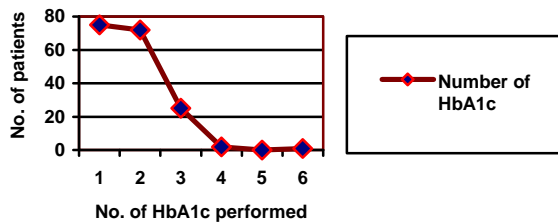


Figure-2: Number of HbA1c performed per patient / year.

HbA1c is now also been recognized as a diagnostic tool for diabetes^{8,9} with the conditions that rigorous quality assurance tests are in place and assays are standardized to the international reference values, and there are no conditions present which prohibit its accurate measurement².

According to WHO (2006), ADA,¹⁰ CDA,³ NICE,¹¹ and IDF,¹² HbA1c should be measured regularly in every patient at 2-6 months interval, based on individual risks of macrovascular and microvascular complications^{13,14}.

After the publication of results of renowned trials, Diabetes Control and Complications Trial (DCCT),^{5,15} and United Kingdom Prospective Diabetes Study (UKPDS),⁵ the clinical utility of HbA1c as a risk assessment tool of diabetes

complications in type 1 (insulin-dependent) and type 2 (non-insulin-dependent) patients respectively has been established^{2,4}. Analysis of the Pittsburgh Epidemiology of Diabetes Complications Study also suggested that long-term fluctuations in HbA1c variability influence complications more than short-term fluctuations⁴. Another study, Epidemiology of diabetes interventions and complications (EDIC) will continue till 2016, is designed, utilizing the results from the DCCT,¹⁵ as a baseline to further assess the role of HbA1c in the long-term complications related to heart and blood vessels in relation to intensive glucose control affects in type 1 diabetes^{16,17}.

The aim of the study is to determine how appropriately HbA1c testing is being used in our setting. So far, not much work has been done in this regard.

MATERIAL AND METHODS

This is a laboratory-based, descriptive study, performed at Chemical Pathology Department, Shifa International Hospital, Islamabad, Pakistan, a private ISO certified tertiary care hospital. The data was collected from October 2011 to October 2012. Known diabetic patients having regular follow-up in various departments of hospital and having their routine laboratory investigations in our laboratory, constituted the study population. A total of 170 patients were selected through Laboratory Information System by non-probability purposive sampling method, and were retrospectively analyzed with the following inclusion criteria: all known diabetic male and female patients, individuals above 6 years of age, patients already on treatment for diabetes at our hospital.

Appropriate interval for HbA1c testing was defined as all patients tested within 2-6 months¹⁰⁻¹⁴. Tests ordered within a 2 months period and those orders after 6 months were labeled as too early and too late, respectively.

Four guidelines namely WHO, ADA, CDA and NICE for HbA1c testing were utilized for the data interpretation

Strategy:

Hemolysate was prepared using MULTIGENT Hemoglobin Denaturant. The samples were run on Architect c 8000, Abbott, operating on the principle of immunoturbidimetry using micro-particle agglutination inhibition method.

Data analysis procedure:

Frequency and percentage were calculated for qualitative variables like gender, distribution of HbA1c test intervals per patient keeping in view guidelines.

RESULTS

Out of a total of 170 patients, 47.06% (n= 80) were males and 52.94% were females (n= 90). Majority of the patients were above the age of 60 years. Four patients were less than 20 years of age, 4 between 20-30 years, 12 between 31-40 years, 16 between 41-50 years, 51 between 51-60 years, and 83 patients above 60 years of age.

Figure-1 shows the grouping of patients on the basis of test orders of glycated hemoglobin. Only 35.8% (n= 61) were being properly monitored as per guidelines. Out of 64.2% (n=109) patients who were inappropriately monitored, 12.9% (n=22) had repeat orders within 2 months (too early) while 51.1% (n=87) of patients were being monitored at longer interval next test order after more than 6 months. Another finding was that 45.2% (n=77) had only one test order in the whole study year.

Number of HbA1c performed per patient during study period was also noticed. More than 70 patients had their HbA1c monitored once a year (Figure-2).

We also analyzed our data in terms of HbA1c levels and found that majority of the patients with high HbA1c levels were the one who were having late monitoring (Figure-3).

DISCUSSION

Diabetes is a burden on the economy of a developing nation like Pakistan due to debilitating complications like retinopathy,

nephropathy and cardiovascular problems. In

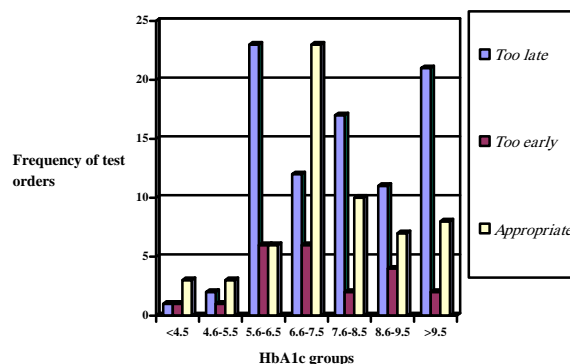


Figure-3 Frequency of test orders of each category following in different HbA1c groups.

this study, we attempted to find the compliance with recommended guidelines for HbA1c, with regard to monitoring of diabetic patients.

In a study by Walraven et al¹⁹, it was pointed out that towards irrational utilization of laboratory tests in general, with HbA1c, forming sinusoidal shape repetition curve. It was repeated in 6.4% in 1 week, for 26% in 3 months, and 39.7% once a year.

Another study, published by Wijk et al²⁰, shows that hemoglobin A1c is one of the most frequently ordered test; making 71.2% of the noncompliant order forms.

In Evidence Practice Gaps Report Volume 1: A review of developments 2004 - 2007,²¹ has documented that an analysis of Medicare data from 1999-2000 showed that around 75% of diabetic patients were not having their HbA1c measured as per guidelines. Another review from 2004-2007, found no change in monitoring practices. Numerous estimates published for 1999-2005, ranges from 25 to 80% are having HbA1c monitoring every 6 months.

In a study by Lyon et al²², approximately 60% of patients had only a single test during the 2-year interval, while a study by Salinas, et al²³ shows 76.56% with only 1 HbA1c test/year in 2009.

Similarly demonstrated in a study performed by Akan et al²⁴, 10.3% of all orders were performed within 29 days and 35.5% of all orders were within 89 days.

Results of a study by Driskell et al²⁵, highlight that only 49% of requests are according to guidelines; 21% were too soon and 30% were too late.

Our study is in agreement to a great degree with the above-mentioned studies, highlighting that many test orders are not according to the updated guidelines and hence underutilizing such an important parameter.

Worldwide there is dramatic increase in ordering of glycated hemoglobin. Even in our laboratory, we have observed increase over the last 3 years, being 6,087 in 2009 to 10,025 during 2012. But still there is an immense need to enforce the rationale use of HbA1c in day-to-date practice to prevent the long-term drastic complications in diabetic population.

Our study group represents only a selected group of diabetic population having their routine follow-up at our hospital. It is hoped that our study will help in predicting the trends being followed in various health care facilities. Further, work in this regard will be necessary to comprehend the role of HbA1c for the general practitioners and physicians.

CONCLUSION

The study highlights that in large proportion of diabetic patients; glycated hemoglobin is not being properly utilized as a tool to assess the risk of long-term diabetic complications.

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