



Evaluation of HbA1c in the Diagnosis of Diabetes

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ABSTRACT

Background: Diabetes has become a major health problem in India with the largest number of diabetic patient burden in the world. It is estimated that, this disease will assume epidemic proportions during the first quarter of the 21st century and by the year 2025, >75% of people with diabetes will reside in developing countries, as compared with 62% in 1995. We evaluated the clinical utility of HbA1c as the base line investigation along with plasma glucose estimation in hospitalized patients for diagnosis of diabetes mellitus.

Methods: A total of 400 patients of more than 25 yrs were tested. All the patients were evaluated by a random plasma glucose estimation, plasma glucose fasting and 2h after 75 g of glucose and HbA1c.

Result: Fasting plasma levels varied from 82mg/dl to 216 mg/dl A total of 11 patients had plasma glucose values in the diabetic range (>126mg/dl) Plasma glucose in these patients ranged from 129 to 216 mg/dl. Patients with diabetes had higher HbA1c levels than subjects without diabetes. We found that an HbA1c value $\geq 6.5\%$ was 100% (11/11) specific for the diagnosis of diabetes.

Conclusion: HbA1c correlated well with fasting plasma glucose values. In clinical settings, this test would be preferred as a first line test for diagnosis of diabetes in our country as it is convenient for the patient.

Keywords: Diabetes mellitus, HbA1c, Plasma Glucose Measurement.

Introduction

Diabetes has become a major health problem in India with the largest number of diabetic patient burden in the world. It is estimated that, this disease will assume epidemic proportions during the first quarter of the 21st century and by the year 2025, >75% of people with diabetes will reside in developing countries, as compared with 62% in 1995. The countries with the largest number of people with diabetes are, and will be in the year 2025, India, China, and the U.S (1). In Indians, onset of diabetes occurs at a younger age and gives ample time for development of chronic vascular complications thus adding to the economic burden (2)

It becomes important that we diagnose the disease early to initiate treatment at the earliest. Standard test for diagnosis of diabetes are the plasma glucose fasting and post 2h glucose plasma glucose estimations (3). International expert committee has recommended HbA1c for the diagnosis of diabetes mellitus as it correlates well with fasting plasma glucose (4).

How useful this is in our settings needs to be evaluated. We evaluated the clinical utility of HbA1c as the base line investigation along with plasma glucose estimation in hospitalized patients for diagnosis of diabetes mellitus.

Materials and Methods

The sample population consisted of randomly selected patients being admitted in our hospital for varying

diagnoses. There was no history of diabetes in these patients but they had one or more risk factors. All persons with a family history of diabetes and/or high blood pressure and lipid abnormalities were included. Children and pregnant women were excluded from the study. A total of 400 patients of more than 25 yrs were tested. All the patients were evaluated by a random plasma glucose estimation, plasma glucose fasting and 2h after 75 g of glucose and HbA1c.

The plasma glucose levels were estimated using Glucose Oxidase method. Each run included assayed normal and abnormal controls. HbA1c was estimated using the Nycocard reader, (NGSP certified method). With a sample volume of 5 μ L, on anticoagulated venous blood (EDTA). This test is based on Boronate affinity test principle with no interference from Hb variants like HbC, HbE, HbF, HbJ and HbS. Those subjects in whom diabetes were diagnosed by fasting plasma glucose, repeat test was done on another occasion to confirm the diagnosis(2).

Result

A total of 400 patients were evaluated. Males constituted 65 % of the patients. Age of the patients ranged from 25 to 79 years. Fasting and post prandial blood glucose criteria were as per the guidelines of WHO. For HbA1c, We used a cut off value of 6.5% for the diagnosis of diabetes mellitus (4). Fasting plasma levels varied from

82mg/dl to 216 mg/dl A total of 11 patients had plasma glucose values in the diabetic range (>126mg/dl) Plasma glucose in these patients ranged from 129 to 216 mg/dl. There was no significant age, sex, or admitting diagnosis differences between the. diabetes and nondiabetes groups. Random plasma glucose values varied from 80 to 180mg/dl. There was no difference in the random plasma glucose values in both categories of patients. Patients with diabetes had higher HbA_{1c} levels than subjects without diabetes. We found that an HbA_{1c} value $\geq 6.5\%$ was 100% (11/11) specific for the diagnosis of diabetes.

Discussion

For many years, blood glucose levels have remained the standard tests for diagnosis of diabetes. Estimating glucose values have problems of collection of a fasting sample. According to WHO, diabetes is diagnosed if the (venous) fasting plasma glucose (FPG) value is ≥ 126 mg dl, or if the casual plasma glucose value is ≥ 200 mg dl, or if the plasma glucose value 2 hours after a 75g oral load of glucose ≥ 200 mg dl. Intermediate categories i.e. Impaired fasting glycemia (≥ 110 and <126 mg/dl) and Impaired Glucose Tolerance (F, 126mg/dl, ≥ 140 mg/dl). In asymptomatic subjects, performing the test on one occasion is not enough to establish the diagnosis (i.e. basis to treat diabetes). Patient has to come back on another occasion for the test (3).

HbA_{1c} is a simple test for glycated haemoglobin and reflects glycemic control over the last six to eight weeks. International expert committee recommends A1C assay for the diagnosis of diabetes as it is an accurate, precise measure of chronic glycemic levels and correlates well with the risk of diabetes complications.

Many studies in western literature, have advocated the use of HbA_{1c} for diagnosis of diabetes (5, 6, 7). When both FPG and A1C were measured, a stronger correlation was found between A1C and retinopathy than between fasting glucose levels and retinopathy (7) Studies that have assessed glycemia with A1C or with single or longitudinal measurements of glucose levels have consistently demonstrated a strong correlation between retinopathy and A1C (8).

In our country, patient compliance is a major problem. For plasma glucose testing, patient have to come back on one more occasion, leading to reduced compliance and delay in initiating treatment. Glucose testing has inherent problems of preanalytic errors due to sample handling (9). In this study we minimized the problems by monitored sample collection and immediate analysis.

In this study HbA_{1c} levels have correlated well with fasting glucose values. In high risk groups this could well become the method of choice for diagnosing diabetes, as it reflects on glucose metabolism over a long period .The HbA_{1c} level was useful in differentiating between patients with and without diabetes.. Patient compliance may be better if only one sample is taken. HbA_{1c} is a handy test which can help in early diagnosis of diabetes by testing a large number of people. This can be obtained at any time and requires no patient preparation.

We evaluated HbA_{1c} in asymptomatic individuals. Selection of patients was risk based so as to detect maximum patients. We tested admitted patients as it was easier to assess the risk, minimize preanalytical variables and collect the sample. All patients who were diagnosed as diabetics by Fasting Plasma Glucose could be diagnosed by HbA_{1c}.

Limitations of this study were the small sample size. We also did not evaluate the prediabetic state as that was out of the scope of study. Further studies are required to test costeffectiveness of the test for its use in screening of patients.

Conclusion

This study was aimed at evaluating the utility of HbA_{1c} in diagnosing diabetes in admitted patients in our hospital. HbA_{1c} correlated well with fasting plasma glucose values. In clinical settings, this test would be preferred as a first line test for diagnosis of diabetes in our country as it is convenient for the patient. Further large scale studies are required, with evaluation of cost effectiveness to include this as a diagnostic criterion for diagnosis of diabetes.

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