



A STUDY TO COMPARE EFFICIENCY OF HbA1C, FASTING & POST-PRANDIAL BLOOD GLUCOSE LEVELS, IN THE DIAGNOSIS OF TYPE-2 DIABETES MELLITUS AND ITS PROGNOSTIC OUTCOME

Pathology

Dr Mandira Sharma

Associate Professor, Department of Pathology, Career Institute of Medical Sciences and Hospital, Lucknow. U.P, India.

Dr Sharad Sharma*

Senior Scientist, Central Drug Research Institute, Lucknow * Corresponding Author

ABSTRACT

Background: HbA1C a marker of chronic hyperglycemia, is associated with diabetes and its complications and has been recommended as a diagnostic test. It is an indicator of average blood glucose concentration over the period of 2-3 months.

Objectives: The main objective of this study was to compare the efficiency of HbA1C, fasting & post prandial blood glucose levels, in the diagnosis of type-2 diabetes mellitus.

Material and Methods: This study was conducted in Career Institute of Medical Sciences and Hospital, a tertiary care referral hospital over a period of 6 months (July 2017-December 2017). Total 300 subjects included in this study were divided into 2 groups.

Results: The study and control group were almost of the similar ages. FBS & 2 hour PP of control groups are 95.5 ± 9.8 & 168.45 ± 22.8 (mg/dl) respectively & that of type 2DM is 198.5 ± 25.6 & 295.8 ± 32.6 respectively. The HbA1C % of all the 30 cases of DR & all the cases with microalbuminuria was $>7.5\%$.

Conclusion: HbA1C can be used effectively for the diagnosis of type 2 DM & it can be used for predicting the complications of type 2 DM. It shows a direct & linear correlation with the diabetic retinopathy and micro-albuminuria. It is very safe to say that HbA1C is better parameter than FBS & 2 hour PPBS level in diagnosing & predicting the complications of diabetes.

KEYWORDS

Type-2 Diabetes Mellitus, Fasting Blood Glucose, Hba1c, Diabetic Retinopathy, Microalbuminuria

Introduction:

Diabetes Mellitus (DM) is a complex, chronic metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It has been predicted that the countries with the largest number of people with diabetes mellitus will be from India, China, and United States in the year 2025.¹

Glycosylated haemoglobin (HbA1c) is a term used to describe a series of stable minor haemoglobin components formed slowly and nonenzymatically from haemoglobin and glucose. HbA1c most accurately reflects the previous 2-3 months of glycaemic control, does not require fasting, has less day-to-day biologic variability, and is a well-accepted marker of risk of long-term microvascular complications.^{2,3}

In 1997, the first American Diabetic Association (ADA) Expert Committee on the Diagnosis and Classification of Diabetes Mellitus suggested the diagnostic cut point of either 126 mg/dl (7.0 mmol/l) for fasting plasma glucose (FPG) and 2 hour post glucose (2hPG) value of 200 mg/dl (11.1 mmol/l) independently to define diabetes. The FPG level is easy to obtain and is suggested as the single test to use for diabetes screening. However, there are reports showing a lack of concordance between the FPG and the 2hPG criteria. Such discrepancies reduce the efficacy of using FPG alone in diabetes screening. It is difficult for physicians and patients to use the oral glucose tolerance test (OGTT) because of its drawbacks, especially for those patients already having an FPG <7.0 mmol/l. It is also impractical to conduct the OGTT for everyone in a diabetes screening. Therefore, an additional, simple, cost-effective, efficient, and tolerable diagnostic process for detecting these cases of diabetes would be highly desirable for diabetes screening.⁴

Table 1: ADA 2015 guidelines for diagnosis of Diabetes Mellitus

Criteria for diabetes diagnosis: 4 options
A1C $\geq 6.5\%$ * Perform in lab using NGSP-certified method and standardized to DCCT assay
FPG ≥ 126 mg/dL (7.0 mmol/L)* Fasting defined as no caloric intake for ≥ 8 hours
2-hour PG ≥ 200 mg/dL (11.1 mmol/L) during OGTT (75-g)* Performed as described by the WHO, using glucose load containing the equivalent of 75g anhydrous glucose dissolved in water
Random PG ≥ 200 mg/dL (11.1 mmol/L) In persons with symptoms of hyperglycemia or hyperglycemic crisis
*In the absence of unequivocal hyperglycemia results should be confirmed using repeat testing

Aim and objectives:

The main objectives of this study was to compare the efficiency of HbA1c, fasting & post prandial blood glucose levels, in the diagnosis of type-2 Diabetes Mellitus.

Material and methods:

This study was conducted in Career Institute of Medical Sciences and Hospital, a tertiary care referral hospital over a period of 6 months (July 2017-December 2017). Total 300 subjects included in this study were divided into 2 groups:

- Group I: included 150 normal healthy individuals, who were in the age group 35-70 years, of either sex and without any family history of diabetes mellitus.
- Group II: included 150 diagnosed patients of type 2 DM in the same age group i.e., 35-70 years.

Inclusion criteria: Type-2 DM diagnosed on the basis of the ADA 2015 guidelines were included in the study.

Exclusion criteria: Type 1 DM, congestive heart failure, tuberculosis, gout, rheumatoid arthritis, renal failure and those who were on hypoglycemic drugs and on insulin therapy were excluded from the study.

Fasting blood samples (FBS), 2 hour Post prandial (PP), Random blood sugar (RBS), HbA1C, were analysed on Dimension RxL Max. Siemens diagnostic company.

24-hours urine was taken for estimation of microalbuminuria by immune-turbidometric method in healthy & diabetic patients.

Statistical analysis of data: All data were expressed as Mean \pm SD. Statistical analysis was done using unpaired students t test. A level of p value <0.05 was used to indicate statistical significance in all analyses.

Results:

Table 2: Gender wise distribution of study subjects

Gender	Group 1	Group 2	Statistics
Male	85	90	<0.05
Female	65	60	<0.05
Total	150	150	

Table 3: Comparison of various parameters in group 1 and group 2

Parameters	Group I (healthy) (Mean \pm SD)	Group II (type2; DM) (Mean \pm SD)	P value

Age (years)	53.45 ± 10.8	51.75 ± 9.9	<0.05
FBS (mg/dl)	95.5 ± 9.8	198.5 ± 25.6	<0.05
2hr PPBS (mg/dl)	168.45 ± 22.8	295.8 ± 32.6	<0.05
RBS (mg/dl)	152.2 ± 13.8	276.4 ± 27.8	<0.05
Hba1c (%)	4.85 ± 0.52	8.65 ± 2.26	<0.05
Microalbuminuria (mg/24 hours)	15.25 ± 2.56	38.64 ± 4.7	<0.05
Diabetic retinopathy (DR)	Not seen	20% showed DR	<0.05

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The mean age of the cases and controls were (51.75 ± 9.9) years (with 175 males and 125 females) and 53.45 ± 10.8 years (with 140 males and 110 females) respectively. Both the study and control group were almost of the similar ages. FBS & 2hr PP of control groups are 95.5 ± 9.8 & 168.45 ± 22.8 (mg/dl) respectively & that of type 2DM is 198.5 ± 25.6 & 295.8 ± 32.6 respectively.

The HbA1C % of all the 30 cases of DR & all cases of microalbuminuria was >7.5%.

Discussion:

Among several studies reported that there is a positive correlation between HbA1C and the duration of diabetic mellitus and it is a strong predictor of risk for diabetes complications.⁵ Use of HbA1C can play a major role in case finding, in hospitalized patients with random hyperglycemia as it does not require fasting, necessitates fewer blood draws, unaffected by recent food intake or recent change in blood sugar levels.⁶

This study also showed lower levels of serum calcium levels in group-II as compared to group-I. Previous studies also suggest that altered calcium homeostasis may play a role in the development of type 2 diabetes as calcium intake is inversely associated with development of type 2 diabetes mellitus. Also, intake of calcium supplements were associated with a lower risk of type 2 diabetes mellitus.^{7,8}

Conclusion:

The various conclusions draws from this study are:

1) HbA1C can be used effectively for the diagnosis of type 2 DM. There is an inherent logic to using a more chronic versus an acute marker of dysglycemia, particularly since the HbA1C is already widely familiar to clinicians as a marker of glycemic control. Moreover HbA1C several advantages to the FPG, including greater convenience, since fasting is not required, evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. This fact is very well supported by WHO & ADA guidelines.

2) HbA1c can be used for predicting the complications of type 2 DM. It shows a direct & linear correlation with the diabetic retinopathy and microalbuminuria. It is very safe to say that HbA1C is the better parameter than FBS & 2 hour PP BS level in diagnosing & predicting complications of diabetes.

The WHO diabetic committee, ADA & the author highly recommends, to use HbA1C for diagnosis & a prognostic biomarker for the diagnosis of type2 DM.

Limitations of study:

As it is a single centre study with a relatively small study population, results cannot be generalized to the entire population.

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