



Original Article

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Role of HbA₁C and OGTT in diagnosing diabetes mellitus

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Abstract

Aims and objectives: This study was done to ascertain the usefulness of HbA₁C as both screening and diagnostic test.

Background: India has become an epicentre of diabetes in the world with an estimated number more than 69.1 millions by the end of 2015. Traditional screening and diagnosing of diabetes in a large population is done by WHO criteria with fasting and postprandial plasma glucose. Recently ADA has included HbA_{1c} as one of the criterion to diagnose DM. Hb₁Ac is a haemoglobin variant not affected by time, meals, can be done in a single test, convenient to the patient. HbA_{1c} not only acts as a better diagnostic tool to diagnose diabetes but can also screen large population.

Material Methods: The cross sectional study was carried out from the period June 2015-November 2016 of in Santhiram Medical College, Nandyal, Department of Biochemistry, Andhra Pradesh, India. 300 patients are selected out of which 60 were previously diagnosed with Diabetes Mellitus were included in the study. Their ages ranged between 43 and 79 years. Thirty matched normal individuals were taken as control group. Glucose levels of OGTT (Oral Glucose Tolerance Test) and HbA₁C were analysed in 240 patients. HbA₁C estimated in ion exchange chromatography. Glucose –GOD POD method estimated in a semi automated analyser.

Results: Of the 240 patients on whom OGTT was performed 35 patients were diagnosed with DM, 95 patients with Pre DM, 110 had normal glucose metabolism. An HbA₁C > 6.5% detected diabetes with 71.43% sensitivity and 86.6% specificity compared with OGTT. The total prevalence of DM and Pre DM is 60% based on HbA₁C and 54% based on OGTT.

Conclusion: HbA_{1c} is a more sensitive screening test than OGTT, but lacks specificity. OGTT is more specific. HbA_{1c} remains the gold standard in assessment of glycemic control with availability of standardized methods. So HbA_{1c} is not only marker for monitoring DM but also predictor of prediabetes mellitus.

Keywords: Diabetes Mellitus; HbA₁C; OGTT; Prediabetes.

Introduction

Global prevalence of diabetes mellitus doubled from 1980 to 2014, reflecting increase in overweight and obesity. India has become an epicentre of diabetes in the world with an estimated number more than 69.2 millions by

the end of 2015. Unfortunately, over half of these people remain undiagnosed as diabetes is a “silent” disease. [1] The need for a simple screening tool for detecting undiagnosed people with high risk persons need to be screened.

Previously OGTT was performed to diagnose diabetes mellitus in high risk patients .Because of discomfort of patients, measurement of glycosylated hemoglobin (GHb) has been suggested as an alternative to OGTT for diabetes screening (2,3,4) The gold standard for assessment of glycaemic control at follow up is the glycosylated haemoglobin level. [5].

Materials and Methods

i. Selection and Description of Participants

The cross sectional study was carried out from the period June2015-November 2016 of in Santhiram Medical College, Nandyal, Department of Biochemistry, Andhra Pradesh, India. The study was approved by Ethical and Research Committee of Shantiram General Hospital to use human subjects in the research study 300 patients are selected out of which 60 were previously

diagnosed with Diabetes Mellitus were included in the study based on exclusion criteriae.

Exclusion criteria

1. Known diabetes cases were excluded.,
2. Diabetes Mellitus Type 1,
3. Maturity Onset Diabetes of Young,
4. Gestational Diabetes Mellitus. Their ages ranged between 43 and 79 years.

ii. Technical Information,

All underwent a 75 g OGTT after an overnight fast. HbA1c was measured from a blood sample obtained on the same day by an automated ion-exchanged chromatography (BIO-RAD mini column). The patients were diagnosed as diabetic and prediabetes as per recommendations of WHO and National Diabetes Data Group (American Diabetes Association 2011) [1]. 2016 American Diabetes Association (ADA) Diabetes Guidelines[6].

Criteria for Diabetes Diagnosis: 4 options
FPG ≥126 mg/dL (7.0 mmol/L)* Fasting is defined as no caloric intake for ≥8 hours
2-hr PG ≥200 mg/dL (11.1 mmol/L) during OGTT (75-g)* Using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water
A1C ≥6.5% (48 mmol/mol)* Performed in a lab using NGSP-certified method and standardized to DCCT assay
Random PG ≥200 mg/dL (11.1 mmol/L) In individuals with symptoms of hyperglycemia or hyperglycemic crisis

iii. Statistics: Statistical analysis was performed using standard statistical software (SPSS version 16.0).

Results

Of the 240 patients on whom OGTT was performed 35 patients were diagnosed with DM, 95 patients with Pre DM, 110 had normal glucose metabolism. On the other hand, 104 patients had

prediabetes 96 were diabetes as indicated by A1c values (p=0.001). However, through a chi-squared test, they showed a significant difference between OGTT and A1c for diagnosis (p<0.0001). HbA₁C > 6.5% detected diabetes with 71.43% sensitivity and 86.6% specificity compared with OGTT. The total prevalence of DM and Pre DM is 60% based on HbA₁C and 54% based on OGTT.

Table 1: Distribution of Subjects

Total no. of subjects	Screening	already diagnosed AS DM
300	240	60

Graph 1: shows distribution of subjects

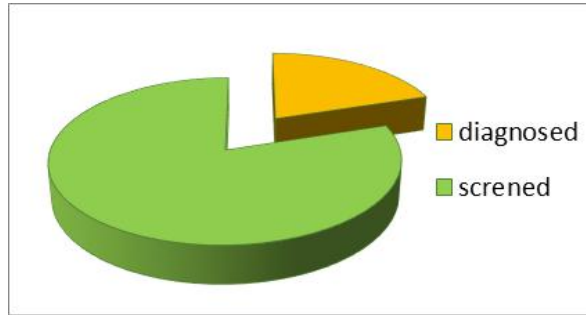
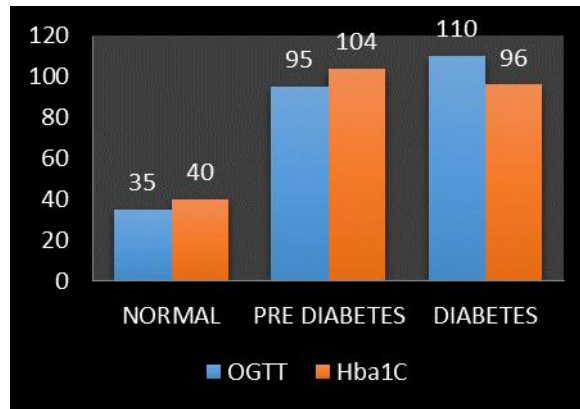


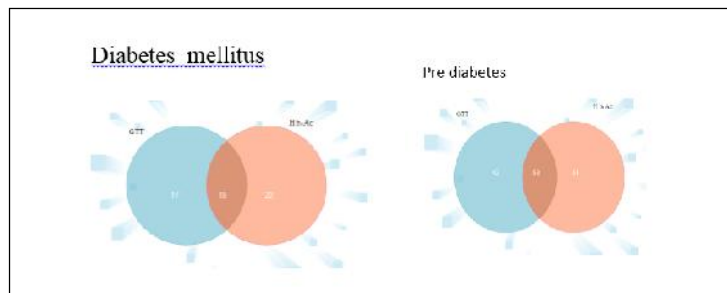
Table 2 :Comparison of diabetic status by mini-OGTT and HbA1C

Status	OGTT	HbA1C
Normal	35	40
Pre diabetes	95	104
Diabetes	110	96

Graph 2 : Comparison of diabetic status by mini-OGTT and HbA1C



Venn diagram



A

B

A. The prevalence of newly diagnosed DM by OGTT results (red circle) and by HbA1c value 6.5% (48 mmol/mol) (blue circle). The prevalence of diabetes mellitus was higher when using HbA1c criteria, and HbA1c classified 60% of the 42 patients with newly diagnosed diabetes mellitus in concordance with OGTT results

B. The prevalence of Prediabetes by OGTT results (red circle) and by HbA1c value 5.7% - 6.4% (blue circle). The prevalence of Prediabetes was higher when using HbA1c criteria compared with OGTT results.

Table 3: Sensitivity, Specificity and Predictive Values of OGTT and HbA₁C

Diabetes	GTT	HbA₁C
Sensitivity	68.63%	71.43%
specificity	83.33%	86.61%
Positive predictive value	61.4%	70.18%
Negative predictive value	87.30%	87.30%

Discussion

Hb1Ac is a haemoglobin variant that is found when glucose binds covalently to beta chain of Hb A. Level of Hb1Ac reflects average. Plasma glucose concentration the proceeding 2-3 months. The diagnosis of diabetes until recently has been based upon detection of elevated plasma glucose levels either fasting or post prandial after a load of 75gms OGTT. While the OGTT is the more sensitive test [7], it has a lengthy cumbersome procedure, poor reproducibility, and questionable cost-effectiveness [8-9]The measurement of HbA1c has been included as one of the criteria to diagnose Diabetes mellitus as per ADA criteria. Advantages: It is convenient single simple method, predicts micro vascular and macro vascular complications with day to day variability, reflects long term glucose control. Our study shows a higher sensitivity and specificity 71.43% and 86.61% when compared with sensitivity, specificity of OGTT 68.63% & 83.33% This is in accordance with other studies . The prevalence of diabetes mellitus amongst high risk groups was estimated as 18% (Hauson RL et al, 1993), 43% (Forrest RD et al, 1987), 29% (Jeppson JO et al, 1986), 33% (Have PM et al, 1984), 33% (Baucher BJ et al, 1981) [10]. We have found a prevalence of 54%by OGTT and 60% and HbA1c and is comparable with the above studies. Diabetes can be delayed or prevented in people who are overweight and have impaired glucose tolerance (IGT). Diet and physical activity interventions are more effective

than medication. People with diabetes can live long and healthy lives if their diabetes is detected and well-managed. The starting point for living well with diabetes is an early diagnosis – the longer a person lives with undiagnosed and untreated diabetes, the worse the health outcomes are likely to be.

Conclusion

We conclude that detection of prediabetic stage by estimation of HbA₁C, will halt the progression to diabetes mellitus. HbA1c was more sensitive, whereas OGTT was more specific. The diagnostic efficiency of 6.5%cut-off recommended by ADA is found to diagnose as well as screen large populations. So HBA1c is not only marker for monitoring DM but also predictor of prediabetes mellitus.

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Conflicts of interest

The authors declare that they have no competing interests or The authors declare the following conflict of interest.

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