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Detection of Diabetes Mellitus Using HbA1C as Diagnostic Criteria

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Abstract

Background: *The evidence base in support of HbA_{1c} (glycosylated Hemoglobin) as a diagnostic test for diabetes mellitus is focused on predicting a clinical outcome, considered to be the pinnacle of the Stockholm Hierarchy applied to reference intervals and clinical decision limits. In the case of diabetes, the major outcome of interest is the long term microvascular complications for which a large body of data has been accumulated, leading to the endorsement of HbA_{1c} for diagnosis in many countries worldwide, with some variations in cut-offs and testing strategies.*

Aims: *To assess the role of Glycosylated Hemoglobin (HbA1C) measurement as a diagnostic test for Diabetes mellitus and to study the relationship of HbA1c and complications of diabetes mellitus.*

Materials And Methods: *The present clinical study was a prospective comparative study conducted over period of 8 months. Total 1025 diabetic patients who were having symptoms suggestive of diabetes mellitus like polyuria, polyphagia, polydypsia and easy fatigability and never been diagnosed as diabetic were examined out of them 820 were excluded from the study on the basis of exclusion criteria. Remaining 205 patients who satisfied the inclusion criteria were subjected to detailed history, thorough clinical examination, fundoscopic examination and HbA1c test.*

Inclusion Criteria: *Patients who were having symptoms suggestive of diabetes mellitus like polyuria, polydypsia, polyphagia and easy fatigability, and never being diagnosed as diabetic.*

Exclusion criteria: *Patients who were already diagnosed as diabetics were excluded from the study and Patients having various conditions leading to alternation in levels of HbA1c like altered erythropoiesis, altered hemoglobin, altered glycation.*

Results: *Total 1025 diabetic patients were examined out of them 820 were excluded from the study on the basis of exclusion criteria. Remaining 205 patients who satisfied the inclusion criteria were subjected to detailed history, thorough clinical examination, fundoscopic examination and HbA1c test. On the basis of HbA1c as a diagnostic test for diabetes mellitus out of total 205 patients one hundred four(50.7%) were diagnosed as diabetic and one hundred one(49.3) were non diabetic. On the basis of fasting blood sugar level as a diagnostic test for diabetes mellitus out of total 205 patients. Hundred (48.8%) were diagnosed as diabetic and one hundred five(51.2) were non diabetic. On the basis of post prandial blood sugar level as a diagnostic test for diabetes mellitus out of total 205 patients. Eighty seven(42.4%) were diagnosed as diabetic and one*

hundred eighteen(57.6) were non diabetic. HbA1c is a good diagnostic test. But FBS, PPBS should also be done to have accurate diagnosis of diabetes mellitus and to avoid the under dignosis and rarely over diagnosis. In this study out of two hundred five patients fourty two (20.2%) had Diabetic retinopathy as a complication and sixty two (30.2) as neuropathy as a complication. Both of these two were highly significant complications associated with higher levels of HbA1c (p value 0.000).while out of two hundred five patients. Fourteen (20%) had diabetic ketoacidosis as a complication. which shown significant association with higher levels of HbA1c.(p value 0.001).

Conclusion: *HbA1c is a good diagnostic test and better predictor of glycemia related complications.*

- *But FBS, PPBS should also be done to have accurate diagnosis of diabetes mellitus(DM) and to avoid the under dignosis and rarely over diagnosis.*
- *Diabetic retinopathy, neuropathy, DKA are the complications in DM depending upon the HbA1c level. and they have got significant correlation.*

Introduction

Glycated haemoglobin (HbA1c) is a form of hemoglobin that is measured primarily to identify the three month average plasma glucose concentration.

It is formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose. HbA1c is a measure of the beta-N-1-deoxyfructosyl component of hemoglobin.

Normal levels of glucose produce a normal amount of glycated hemoglobin. As the average amount of plasma glucose increases, the fraction of glycated hemoglobin increases in a predictable way.

In diabetes mellitus, higher amounts of glycated hemoglobin, indicating poorer control of blood glucose levels, have been associated with neuropathy and retinopathy.

AIMS and Objectives

To assess the role of Glycosylated Hemoglobin (HbA1C) measurement as a diagnostic test for Diabetes mellitus and to study the relationship of HbA1c and complications of diabetes mellitus.

Diagnostic criteria of Diabetes Mellitus (W.H.O.)

- FBS- ≥ 126 mgs/dl. (7.0 mmol/l)
- Two hours plasma glucose ≥ 200 mgs/dl. (11.1mmol/l)
- HbA1c ≥ 6.5%

Materials and Methods

Study Design: Prospective comparative study

Study population and study sample: Total 1025 diabetic patients were examined out of them 820 were excluded from the study on the basis of exclusion criteria. Remaining 205 patients who satisfied the inclusion criteria were subjected to detailed history, thorough clinical examination, fundoscopic examination and HbA1c test. They were matched on the basis of age, sex.

Study setting: Department of medicine RDGMC, Ujjain.

Study period: 1/07/2014 to 30/03/2015.

Inclusion criteria

Patients who were having symptoms suggestive of diabetes mellitus like polyuria, polydypsia, polyphagia and easy fatigability, and never being diagnosed as diabetic.

Exclusion criteria

Patients who were already diagnosed as diabetics were excluded from the study and Patients having various conditions leading to alternation in levels of HbA1c like altered erythropoiesis, altered hemoglobin, altered glycation.

Results

Table 1 1)Age wise gender distributaion in cases(n = 205)

Age groups (in years)	NO. OF PATIENTS	
	Males	females
21-40	18(15.1)	16(18.6)
41-60	69(58.0)	57(66.3)
61-80	32(26.9)	13(15.1)
Male : female ratio was 1.38:1.		

The male and female ratio was 1.38:1 and the most patients sixty nine (58%) were from age group 41-60.

Table no.2: Fasting blood sugar(FBS) level in the study cases(n=205)

FBS mg/dl	No. of patients (n=205)	percentage	status
<126	105	51.2	Non-diabetic
≥126	100	48.8	Diabetic

On the basis of fasting blood sugar level as a diagnostic test for diabetes mellitus out of total 205 patients. Hundred (48.8%) were diagnosed as diabetic and one hundred five(51.2) were non diabetic.

Table no.3 Post prandial blood sugar level in the study cases(n=205)

PPBS mg/dl	No. of patients	percentage	status
<200	118	57.6	Non-diabetic
≥200	87	42.4	Diabetic

On the basis of post prandial blood sugar level as a diagnostic test for diabetes mellitus out of total 205 patients. Eighty seven (42.4%) were diagnosed as diabetic and one hundred eighteen(57.6) were non diabetic.

Table no.4 HbA1c level in the study cases(n=205)

HbA1c(%)	No.of patients	percentage	status
<6.5	101	49.3	Non diabetic
≥6.5	104	50.7	Diabetic

On the basis of HbA1c as a diagnostic test for diabetes mellitus out of total 205 patients one hundred four(50.7%) were diagnosed as diabetic and one hundred one(49.3) were non diabetic.

Table no.5 Association of diabetic complications with HbA1c in diabetic and non-diabetic group

Complications	Total	P value	Significance
Diabetic retinopathy	42(20.4)	0.000	Highly significant
Neuropathy	62(30.2)	0.000	Highly significant
DKA	14(20)	0.001	Significant
IHD	41(20)	0.303	Not significant
HTN	98(47.8)	0.853	Not significant
CVA	27(13.2)	0.892	Not significant
PVD	8(3.9)	0.52	Not significant

IHD-ischaemic heart disease, DKA-diabetic ketoacidosis,
HTN-hypertension, CVA-cerebrovascular accident,
PVD-peripheral vascular disease.

In this study out of two hundred five patients fourty two (20.2%) had Diabetic retinopathy as a complication and sixty two (30.2) as neuropathy as a complication. Both of these two were highly significant complications associated with higher levels of HbA1c (p value 0.000).while out of two hundred five patients. Fourteen (20%) had diabetic ketoacidosis as a complication. which shown significant association with higher levels of HbA1c.(p value 0.001).

Table no.6 Correlation of HbA1c with FBS and PPBS in diabetic and non diabetic group

Variables	Diabetic group(n=104)		Non –diabetic group(n=101)	
	Karl pearson correlation	significance	Karl pearson correlation	significance
FBS	0.490	0.000	0.577	0.000
PPBS	0.556	0.000	0.577	0.000

There was significant correlation of HbA1c with FBS and PPBS

Table no.7 Comparison of sensitivity and specificity of HbA1c in relation to FBS in various studies

Study	Year	Sensitivity (%)	Specificity (%)
Ko et al	1998	77.5	88.8
Resnick et al	2000	42.8	99.6
Araneta et al	2010	68.9	95.3
Kumar et al	2010	65	88
Kramer et al	2010	44	79
Cavagnolli et al	2011	20.9	95.3
Present study	2015	87	83.8

NHANES STUDY (2007-2008) using HbA1c against OGTT as the reference test showed that the HbA1c thresold of 6.4% had sensitivity of 72% and specificity of 84%.

The sensitivity and specificity of our study was 87% and 83.8% which is more or less similar to Ko et al (1998), Araneta et al(2010), Kumar et al (2010).

Conclusion

HbA1c is a good diagnostic test and better predictor of glycemia related complications.

But FBS,PPBS should also be done to have accurate diagnosis of diabetes mellitus(DM) and to avoid the under dignosis and rarely over diagnosis.

Diabetic retinopathy, neuropathy, DKA are the complications in DM depending upon the HbA1c level.and they have got significant correlation.

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***Limitations:** The small size of population studied. single centered study.

***Conflict of intrest:** None declared

***Ethical approval:** The study was approved by the institutional ethics committee.

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