

Original Research

Use of glycated hemoglobin in the diagnosis of diabetes mellitus

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ABSTRACT:

Background: According to the International Diabetes Federation, 285 million people worldwide have diabetes, and over the next 20 years, that figure is predicted to increase to 438 million, or 7 million people per year. The present study was conducted to assess use of glycated hemoglobin in the diagnosis of diabetes mellitus. **Materials & Methods:** 76 diabetics of both genders were included in the study. Diabetic patients were put in group I and healthy subjects in group II. 10 ml of venous blood was collected under strict aseptic conditions in a test tube. Assessment of glycated hemoglobin, FPG, 2-h OGTT was done in all subjects. **Results:** Group I had 46 males and 30 females and group II had 38 males and 38 females. The mean FBG level in group I was 138.4 mg/dl and in group II was 96.2 mg/dl. 2-H OGTT was 236.2 mg/dl in group I and 112.8 mg/dl in group II. The mean HbA1c level was 7.6% in group I and 5.2% in group II. The difference was significant ($P < 0.05$). There were 50 patients with HbA1c >6.5 and 26 patients with HbA1c <6.5 . Among 50, 20 had FBG <126 and 30 had >126 . Based on 2-H OGTT, 12 had <140 , 13 had 140-200 and 25 had >200 . Among 26, 12 had FBG <126 and 14 had >126 . Based on 2-H OGTT, 5 had <140 , 7 had 140-200 and 14 had >200 . **Conclusion:** Most of the patients would have their diabetes diagnoses reclassified if the HbA1c were to be used as the diabetes criterion. Clinicians and health systems must be aware of the distinctions and similarities between the 2-hour OGTT and A1c or FPG in the diagnosis of diabetes mellitus and pre-diabetes.

Keywords: Diabetes, glycated hemoglobin, Blood glucose,

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INTRODUCTION

According to the International Diabetes Federation, 285 million people worldwide have diabetes, and over the next 20 years, that figure is predicted to increase to 438 million, or 7 million people per year.¹ The 75-g oral glucose tolerance test (OGTT) and fasting plasma glucose (FPG) are required by the current criteria for diagnosing diabetes; this is a time-consuming procedure that necessitates fasting and is impacted by both short-term lifestyle changes and acute fluctuations in glucose levels. The tests have been the international standard for diagnosis since it was discovered that fasting and post-challenge blood glucose levels may predict the risk of diabetic retinopathy.² Many individuals with diabetes may not meet the FPG and OGTT criteria, which are frequently used to identify persons at risk of type 2 diabetes. As a result, a large number of individuals with diabetes or pre-diabetes went untreated and may

have had long-term effects from the disease when they were finally diagnosed.³

Currently, high-risk glucose levels below the diabetes range are diagnosed using impaired glucose tolerance (IGT) and impaired fasting glucose (IFG). Furthermore, determining a person's type of diabetes frequently depends on the circumstances surrounding the diagnosis, and many diabetics are difficult to categorize into a single class.⁴

Glycated hemoglobin (HbA1c) was the basis for new diagnostic criteria published by the International Expert Committee in 2009. A HbA1c of $\geq 6.5\%$ was considered to be indicative of diabetes, while a HbA1c of 6.0–6.4% indicated "high risk" of developing diabetes.⁵ The American Diabetes Association (ADA) then suggested that an A1c of $\geq 6.5\%$ be used to diagnose diabetes and that an A1c of 5.7–6.4% be used to determine the highest risk of developing diabetes. Retinopathy risk at various

HbA1c levels served as the basis for the suggested diagnostic threshold of 6.5%.⁶The present study was conducted to assess use of glycated hemoglobin in the diagnosis of diabetes mellitus.

MATERIALS & METHODS

The study was carried out on 76 diabetics of both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. Diabetic patients were put in group I and healthy subjects in in group II. 10 ml of venous blood was collected under strict aseptic conditions in a test tube. Assessment of glycated hemoglobin, FPG, 2-h OGTT was done in all subjects. Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Groups	Group I	Group II
Status	Diabetics	Controls
M:F	46:30	38:38

Table I shows that group I had 46 males and 30 females and group II had 38 males and 38 females.

Table II Assessment of parameters

Parameters	Group I	Group II	P value
FBG (mg/dl)	138.4	96.2	0.01
2- H OGTT (mg/dl)	236.2	112.8	0.01
HbA1C (%)	7.6	5.2	0.03

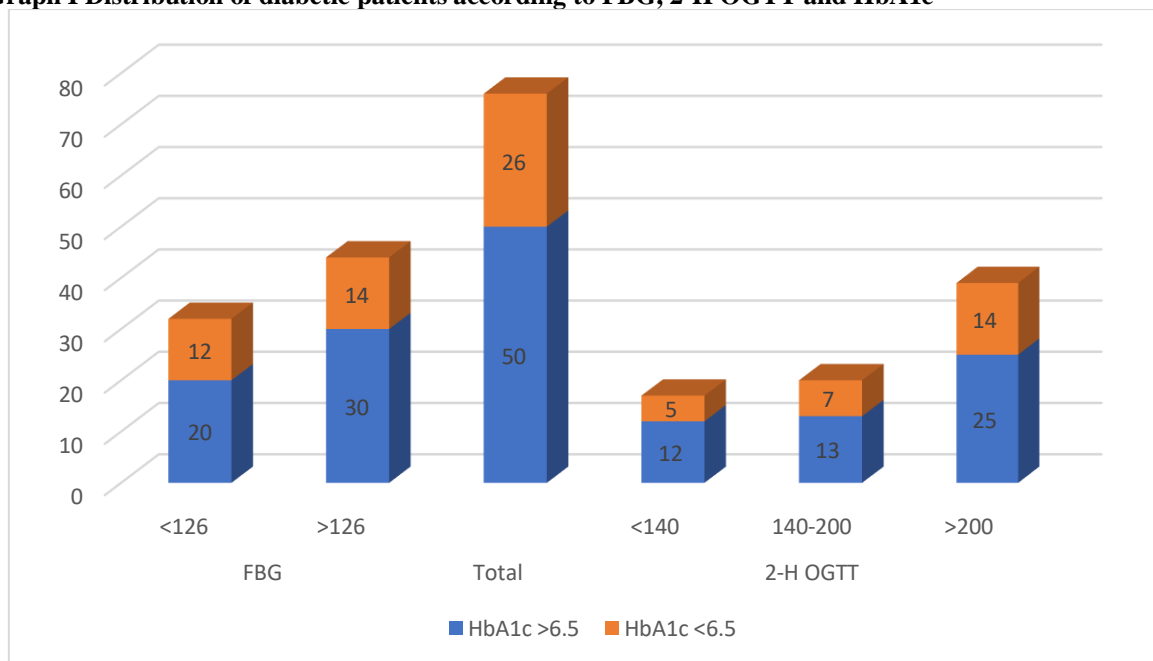
Table II shows that mean FBG level in group I was 138.4 mg/dl and in group II was 96.2 mg/dl. 2- H OGTT was 236.2 mg/dl in group I and 112.8 mg/dl in group II. The mean HbA1C level was 7.6% in group I and 5.2% in group II. The difference was significant (P< 0.05).

Table III Distribution of diabetic patients according to FBG, 2-H OGTT and HbA1c

Parameters	FBG		Total	2-H OGTT			Total
	<126	>126		<140	140-200	>200	
HbA1c >6.5	20	30	50	12	13	25	50
HbA1c <6.5	12	14	26	5	7	14	26
Total	32	44	76	17	20	39	76

Table III, graph I shows that there were 50 patients with HbA1c >6.5 and 26 patients with HbA1c <6.5. Among 50, 20 had FBG <126 and 30 had >126. Based on 2-H OGTT, 12 had <140, 13 had 140-200 and 25 had >200. Among 26, 12 had FBG<126 and 14 had >126. Based on 2-H OGTT, 5 had <140, 7 had 140-200 and 14 had >200.

Graph I Distribution of diabetic patients according to FBG, 2-H OGTT and HbA1c



DISCUSSION

HbA1c testing is highly standardized, exhibits low intra-individual variation, can be obtained at any time, require no patient preparation, and are relatively stable at room temperature after collection. However, this new criteria's accuracy is controversial and has not yet been adopted internationally.⁷ A1c assay is more convenient than OGTT because it has little inter-individual variation if there is not any hematologic disease and easy to use in daily routine practice because it does not need any fasting and diet preparation.^{8,9} The present study was conducted to assess use of glycated hemoglobin in the diagnosis of diabetes mellitus.

We found that group I had 46 males and 30 females and group II had 38 males and 38 females. Alqahtani et al¹⁰ screened a total of 27,001 individuals. The results of FPG, OGTT and HbA1c for 1814 individuals were analyzed and all grouped as diabetic patients, glucose intolerant (pre-diabetes) patients and non-diabetic patients according to new ADA criteria for the diagnosis of diabetes. The prevalence of newly diagnosed diabetes was 69.6% and 54% by using HbA1c alone, 64.2% and 28.2% with 2-h OGTT alone and 43.2% and 60.3%, respectively with FPG alone. Differences between FPG versus 2-h OGTT, FPG versus A1c and OGTT versus A1c were statistically significant ($P < 0.0001$, $P < 0.0001$ and $P = 0.02$, respectively). Diagnostic sensitivity of all diabetic criteria was 69.6% for A1c; Nearly, 64.2% for OGTT and only 43.1% for FPG respectively. In terms of diagnostic ratio of glucose intolerance; difference between HbA1c and OGTT was statistically significant ($P < 0.0001$).

We found that mean FBG level in group I was 138.4 mg/dl and in group II was 96.2 mg/dl. 2-h OGTT was 236.2 mg/dl in group I and 112.8 mg/dl in group II. The mean HbA1c level was 7.6% in group I and 5.2% in group II. Colagiuri et al¹¹ in their study glycemic control and clinical and surrogate outcomes were compared for 5,088 of 5,102 participants according to whether they had low (<140 mg/dl [<7.8 mmol/l]), intermediate (140 to <180 mg/dl [7.8 to <10.0 mmol/l]), or high (≥ 180 mg/dl [≥ 10 mmol/l]) fasting plasma glucose (FPG) levels at diagnosis. Individuals who presented with and without diabetic symptoms were also compared. Fewer people with FPG in the lowest category had retinopathy, abnormal biothesiometer measurements, or reported erectile dysfunction. The rate of increase in FPG and HbA(1c) during the study was identical in all three groups, although absolute differences persisted. Individuals in the low FPG group had a significantly reduced risk for each predefined clinical outcome except stroke, whereas those in the intermediate group had significantly reduced risk for each outcome except stroke and myocardial infarction. The low and intermediate FPG groups had a significantly reduced risk for progression of retinopathy, reduction in

vibration sensory threshold, or development of microalbuminuria.

We found that there were 50 patients with HbA1c >6.5 and 26 patients with HbA1c <6.5 . Among 50, 20 had FBG <126 and 30 had >126 . Based on 2-H OGTT, 12 had <140 , 13 had 140-200 and 25 had >200 . Among 26, 12 had FBG <126 and 14 had >126 . Based on 2-H OGTT, 5 had <140 , 7 had 140-200 and 14 had >200 . Patel et al¹² found that the mean glycated hemoglobin level was lower in the intensive-control group (6.5%) than in the standard-control group (7.3%). Intensive control reduced the incidence of combined major macrovascular and microvascular events (18.1%, vs. 20.0% with standard control; hazard ratio, 0.90; 95% confidence interval [CI], 0.82 to 0.98; $P=0.01$), as well as that of major microvascular events (9.4% vs. 10.9%; hazard ratio, 0.86; 95% CI, 0.77 to 0.97; $P=0.01$), primarily because of a reduction in the incidence of nephropathy (4.1% vs. 5.2%; hazard ratio, 0.79; 95% CI, 0.66 to 0.93; $P=0.006$), with no significant effect on retinopathy ($P=0.50$). There were no significant effects of the type of glucose control on major macrovascular events (hazard ratio with intensive control, 0.94; 95% CI, 0.84 to 1.06; $P=0.32$), death from cardiovascular causes (hazard ratio with intensive control, 0.88; 95% CI, 0.74 to 1.04; $P=0.12$), or death from any cause (hazard ratio with intensive control, 0.93; 95% CI, 0.83 to 1.06; $P=0.28$). Severe hypoglycemia, although uncommon, was more common in the intensive-control group (2.7%, vs. 1.5% in the standard-control group; hazard ratio, 1.86; 95% CI, 1.42 to 2.40; $P<0.001$).

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that most of the patients would have their diabetes diagnoses reclassified if the HbA1c were to be used as the diabetes criterion. Clinicians and health systems must be aware of the distinctions and similarities between the 2-hour OGTT and A1c or FPG in the diagnosis of diabetes mellitus and pre-diabetes.

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