Original Research Article

A study to evaluate HbA1C as an independent diagnostic criterion comparing to fasting plasma glucose and postprandial glucose levels as a standard test for diagnosis of diabetes

Lalitha R.[1], Shetty S.B.[2], Anil Kumar R.[3]

[1]Dr Lalitha R, Assistant Professor, [2]Dr Surekha B. Shetty, Assistant Professor,[3]Dr Anil Kumar R., Assistant Professor, all are affiliated to Karnataka Institute of Endocrinology and Research, Bannerghatta Road, Jayanagar, Bangalore, Karnataka, India.

Corresponding Author: Dr. Lalitha R, Assistant Professor, Karnataka Institute of Endocrinology and Research, Bannerghatta Road, Jayanagar, Bangalore, Karnataka, India. E-mail: drlalithashivaprakash@gmail.com

Abstract

Aims and objectives: 1) To compare and correlate glycosylated haemoglobin (HbA1C) as an independent criteria in diagnosis. 2) To define the sensitivity and specificity of HbA1C estimates at the ADA recommended cut off of ≥ 6.5%. **Study design and methods:** Subjects were first tested for Fasting plasma glucose and two-hours post 75 grams glucose challenge, HbA1c was estimated for the all the subjects. **Results:** The sensitivity and specificity of HbA1C at the ADA recommended ≥ 6.5% cut off value in newly detected diabetic patients was 96.70% and 82.92% respectively with a positive predicted value of 56.05% and a negative predictive value of 99.11 % .75.00 % at a p<0.001. We find that we miss 42% of people with diabetes if fasting plasma glucose levels are considered. Given the risks associated with PPG levels in our population it is important that these criteria be used in screening programmes. **Conclusion:** Our study shows that HbA1C is comparable to FPG levels estimation but is not superior enough to replace blood glucose estimation. Use of post prandial glucose levels are better in detecting diabetes than fasting plasma glucose levels. A combination of post prandial glucose with HbA1C may be a superior single test that can overcome the cumbersome oral glucose tolerance test.

Keywords: HbA1C, Blood Glucose, Diagnosis of diabetes

Introduction

Type 2 Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycaemia due to either defects in insulin secretion or insulin resistance. It is associated with various long term micro vascular complications like retinopathy, nephropathy and neuropathy. Diabetes mellitus is a metabolic disorder characterized by chronic hyperglycaemia resulting from defects in insulin secretion or action or both. Diabetes is a chronic illness associated with significant micro vascular and macro vascular complications.

India leads the world with highest number of diabetic subjects second only to China with the dubious distinction of being termed the "diabetes capital of the world". According to the Diabetes Atlas 2017 published by the International Diabetes Federation, the number of people with diabetes in India is currently around 82 million and is expected to rise to 151 million by 2045 unless urgent preventive steps are taken [1]. A certain specific clinical and biochemical abnormalities in Indians which consists of an increased insulin resistance, greater abdominal adiposity with a higher waist hip ratio in spite of a lower body mass index, lower adiponectin and higher high sensitive C-reactive protein levels is called the Asian Indian phenotype. This phenotype makes these individuals more prone to diabetes and premature coronary artery disease [2]. The early detection of subjects with a high risk of developing type 2 DM is vital to use preventive ways and scale back the chronic complications related to it and too improve cardiovascular morbidity and mortality. Conventionally, diabetes was diagnosed based on plasma glucose criteria, either the fasting plasma glucose (FPG) or the 2-h value post glucose challenge plasma in the 75-g oral glucose tolerance test

Manuscript received: 08th December 2018
Reviewed: 20th December 2018
Author Corrected: 25th December 2018
Accepted for Publication: 31st December 2018

(OGTT) [3]. An International Expert Committee in 2009 that included representatives of the ADA, the International Diabetes Federation (IDF), and the European Association for the Study of Diabetes (EASD) recommended the use of the A1C test to diagnose diabetes, with a threshold of ≥ 6.5%, (5) and the ADA adopted this criterion in 2010 [4].

The diagnostic test should be performed using a method that is certified by the NGSP and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay. The use of point-of-care (POC) A1C assay for diagnostic purposes could be problematic because proficiency testing is not mandated for performing the test even though they may be NGSP certified.

A test result diagnostic of diabetes should be repeated to rule out laboratory error, unless the diagnosis is clear on clinical grounds. It is preferable that the same test be repeated for confirmation, since there will be a greater likelihood of concurrence in this case [2].

For example, if the HbA1C is 7.0% and a repeat result is 6.8%, the diagnosis of diabetes is confirmed. However, if two different tests (such as HbA1C and FPG) are both above the diagnostic threshold values, the diagnosis of diabetes is also confirmed. On the other hand, if two different tests are available in an individual and the results are discordant, the test whose result is above the diagnostic cut point should be repeated, and the diagnosis is made based on the confirmed test.

ADA 2014 Guidelines for diagnosis of Diabetes

ADA Diagnostic Criteria for type 2 diabetes [5].
The American Diabetes Association (ADA) criteria for the diagnosis of diabetes are any of the following:

A hemoglobin A1c (HbA1c) level of 6.5% or higher; the test should be performed in a laboratory using a method that is certified by the National Glyco-haemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay,

Or

A fasting plasma glucose (FPG) level of 126 mg/dL (7 mmol/L) or higher; fasting is defined as no caloric intake for at least 8 hours,

Or

A 2-hour plasma glucose level of 200 mg/dL (11.1 mmol/L) or higher during a 75-g oral glucose tolerance test (OGTT),

Or

A random plasma glucose of 200 mg/dL (11.1 mmol/L) or higher in a patient with classic symptoms of hyperglycemia (i.e., polyuria, polydipsia, polyphagia, weight loss) or hyperglycemic crisis. World Health Organization (WHO) Criteria for diagnosis of diabetes [6].

The World Health Organization (WHO) the expert committee met March 2009 and concluded that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement.

An HbA1c of 6.5% is recommended as the cut point for diagnosing diabetes. A value less than 6.5% does not exclude diabetes diagnosed using glucose tests. The expert group concluded that there is currently insufficient evidence to make any formal recommend-dation on the interpretation of HbA1c levels below 6.5%

Methods and Materials

Study Design: This was a cross sectional study done at Karnataka Institute of Endocrinology, Bangalore between the time period November 2012 to July 2013 in individuals with no history of diabetes and who attended the outpatient department for screening of diabetes. A sample size of the 500 subjects who underwent an oral glucose tolerance test during the time period were taken into consideration. The individuals were first tested for fasting blood glucose (FPG) and then two-hours Post glucose–plasma glucose (PPG) levels after a 75g glucose load. HbA1c was estimated at the same time.

Inclusion Criteria

- Individuals with no history of diabetes previously.
- Individuals with symptoms of diabetes presenting for the first time.
- Subjects attending OPD for screening of diabetes.
- Age more than 18 years.

Exclusion Criteria

- Gestational diabetes
- Pregnant women
- Age below 18 years.
- Renal dysfunction.
- History of anaemia

Investigations

- Fasting plasma glucose levels (FPG)
- Post 75 grams plasma glucose levels (PPG)
- Glycosylated Haemoglobin (HbAIC).
- Serum creatinine.

Statistical Methods: Descriptive and inferential statistical analysis has been used in this study. Microsoft excel, SPSS and med calculator software have been employed to derive at various study parameters. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance. 2x2 table and cross tabulations has been used for analysis for different parameters using SPSS. Coding for the values has been carried out to analyse the data accurately. Any missing data had been discarded to maintain accuracy.

The Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Diagnostic statistics viz. Sensitivity, Specificity, PPV, NPV and accuracy have been computed to find the correlation of FPG, PPG, with different levels of HbA1c. Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Med Calc18.0.1and R environment ver.3.12.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Results

Out of the 500 subjects, 7 of them did not have complete data and were excluded from the analysis. The characteristics of the study subjects and the investigations are shown in table 1. Equal distribution of subjects based on gender as seen in table 2. Age distribution of subjects as shown in table 3, the peak age of onset is between 40 to 60 years with higher incidence seen in 51 to 60 years range of age group.

Of all the 493 subjects, 355 did not have diabetes according to the post glucose challenge criteria. Among these 306 had no diabetes according to both HbA1c and FPG criteria (Table 7). The remaining 49 subjects were not diagnosed to have diabetes according to the ADA or WHO criteria.

Hence a sensitivity and specificity was done in order to check the accuracy of each test using as an independent standard. Considering FPG as a standard for diagnosing type 2 diabetes as compared to PPG we find that the sensitivity and specificity are 87.91%, 85.86 % respectively (Table 10). Comparing FPG as a standard with HbA1C the sensitivity and specificity is 96.70%, 82.92 %. FPG doesn't compare well with PPG compared to HbA1C.Vice versa when PPG is taken as a standard the sensitivity and specificity is 68.79%, 91.34 % respectively.15 to 20 % of subjects may go undetected due to FPG criteria as the disease prevalence is 18.42% compared to 31.91% with PPG. This may be due to the fact that Asian Indian Phenotype may have higher levels of post prandial blood glucoses than fasting blood glucoses.

Comparing PPG as a standard with HbA1C the sensitivity and specificity is 78.99%, 86.27 % respectively. Vice versa using HbA1C as a standard the sensitivity and specificity is 68.79%, 91.34 % respectively.

	FPG = Diabetes	**PPG= Diabetes.**
HbA1c sensitivity	96.70%	78.99%
HbA1c specificity	82.92%	86.27%

We have three different criteria for diagnosing diabetes with a tedious test of glucose challenge and yet the three different criteria have no correlation with each other. The higher sensitivity of HbA1c shows that it is good at identifying subjects with diabetes and not identifying those without diabetes. We find that HbAIC is less sensitive in identifying subjects who are negative for fasting but positive for post glucose criteria but carries a higher specificity for no diabetes.

Discussion

Glycosylated Haemoglobin (HbA1C): Haemoglobin is made up of two globin dimers, each with an associated haem moiety. Adult Haemoglobin comprises of 97% HbA ($\alpha 2, \beta 2$) and 1.5– 3.5%, A2 ($\alpha 2, \delta 2$) whereas the foetal haemoglobin (HbF; $\alpha 2, \gamma 2$) forms <2%. These percentages might modify with bound haemoglobinopathies [7]. As an example, HbF levels are enhanced in the presence of hereditary persistence of HbF, β-thalassemia, sickle cell disease, pregnancy, anaemia, and certain leukaemia's. Levels may additionally be increased in hospitalized patients. The components of HbA were known by charge separation on cation exchange resin and named in keeping with their order of elution as follows:

A0, A1a, A1b, and A1C. A1C is that the haemoglobin element that is composed primarily of glycohaemoglobin. Glycohaemoglobin is made by the non-enzymatic glycation of the N-terminal essential amino acid on the β chain of Haemoglobin. HbA1c levels could vary with patients' race/ethnicity [8,9].

Advantages and disadvantages of HbA1c: Plasma glucose levels are easily and quickly measured. They are cost effective. It additionally reflects the pathophysiology of diabetes better. Assays used for estimation of blood glucose levels are time tested and well standardized [10]. Plasma glucose levels are not affected by erythrocyte turnover and might be employed in patients with dyslipidaemias, hepatic, renal or thyroid dysfunction. It is widely obtainable within the primary health care centre and may be used to effectively diagnose diabetes within the giant rural Indian population. Blood glucose estimates need rigorous eight hours fast. This is often typically not achieved as most of our population is unaware and don't adhere to the fasting requirements. Additionally evening or early morning exercise prior to drawing blood sample could result in spuriously lower estimates [9]. A1C reflects the typical plasma glucose over the past eight to twelve weeks and captures chronic hyperglycaemia. It may be done at any time of the day and doesn't need fasting. It reflects the glycation of proteins and thus correlates with micro and macro vascular complications that are because of glycation of proteins. It can even pick up diabetes patients who are additionally prone to protein glycation and therefore complications. In addition A1C isn't affected by simultaneous stress, diet, exercise or smoking. Baseline A1C are often used for additional monitoring of diabetes treatment and glycaemic management. Assays for A1C are standardized better today. A1C measurements are high-priced and not widely obtainable particularly within the Indian context. Haemoglobinopathies although having a low prevalence of three to four-dimensional in India, interfere with A1C measurement. A1C is additionally affected by different conditions with accelerated red cell turnover like protozoal infection, anaemia. Chronic liver disease affects erythropoiesis and ends up in reduced A1C whereas chronic renal disorder will increase glycation and thus A1C. Hypertriglyceridemia will interfere with the assay with reduced A1C. Hypothyroidism on the other hand offers elevated A1C levels [10].

Comparison with other studies: NHANES study in USA showed that a HbA1C cut point of ≥6.5% identifies one-third fewer cases of diabetes than a fasting glucose [11]. The Strong Heart Study in USA concluded that using HbA1c alone in initial diabetes screening identifies fewer cases of diabetes than FPG while using both criteria may identify more people at risk [12]. A Korean Study concluded that the agreement between the fasting plasma glucose and HbA1c for the diagnosis of diabetes was moderate for Korean adults with a kappa index of 0.50 [14]. The New Hoorn Study in Netherland also showed that the correlations between glucose and HbA1C was moderate in the general population [15]. HbA1C level of ≥5.8%, representing 12% of the population, had the highest combination of sensitivity (72%) and specificity (91%) for identifying newly diagnosed diabetes [16]. An Indian study by Kavya et al showed the sensitivity and specificity of the HbA1C is similar to 2 hrs plasma glucose estimates unlike our study [17].

Table-1: Characteristics of the subjects recruited in the study and the distribution of study variables

	HBA1C	FBS	2hrs
N	493	493	493
Minimum	4.200	63.000	59.000
Maximum	16.300	362.000	521.000
Mean	6.466	113.704	177.557
Geometric mean	6.328	109.928	161.773
Harmonic mean	6.219	107.179	149.329
Median	6.000	103.000	150.500
95% CI	6.000 to 6.100	101.000 to 105.000	144.000 to 159.271
Variance	2.3574	1253.2170	7055.2453
SD	1.5354	35.4008	83.9955
SEM	0.06915	1.5944	3.7791
25 - 75 P	5.600 to 6.800	94.000 to 119.000	116.000 to 215.000
Normal Distr.	<0.0001	<0.0001	<0.0001

Table-2: Gender distribution

Female	252	50.7
Male	245	49.3
Total	**497**	**100.0**

Table-3: Age distribution in study group

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	21-30	21	4.2	4.2	4.2
	31-40	95	19.1	19.1	23.3
	41-50	115	23.1	23.1	46.5
	51-60	159	32.0	32.0	78.5
	61-70	85	11	17.1	95.6
	71-80	17	3.4	3.4	99.0
	81-90	4	.8	.8	99.8
	91-100	1	.2	.2	100.0
	Total	**497**	**100.0**	**100.0**	

Subjects tested for fasting glucose levels.≥ 126mg/dl compared with HbA1c criteria.≥6.5% and post glucose challenge ≥200mg/d

Table-4

		Fasting glucose		Total
		No diabetes	**Diabetes**	
HBA1C	No diabetes	25	3	28=20.28%
	Diabetes	33	77	110=79.71%
Total		**58=42%**	**80=58%**	**138**

a Post Glucose = Diabetes

Table-5

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	32.197 (b)	1	.000		
Continuity Correction(a)	29.809	1	.000		
Likelihood Ratio	34.328	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	31.963	1	.000		
N of Valid Cases	138				

We have considered the post glucose challenge plasma glucose levels as positive for diabetes and find 138 subjects fitting the criteria. Among them 42% people tested negative for fasting plasma glucose levels at a diabetes range. So we may miss 42% who have diabetes with FPG and 20.28 % with only HbA1C criteria.

Table-6: Post glucose = no diabetes

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
HBA1C * Fasting Glucose	355	100.0%	0	.0%	355	100.0%

a= Post Glucose = No Diabetes

355 subjects are diagnosed to not have diabetes with post glucose challenge glucose levels (PPG)

Table-7: Hba1c Vs Fasting Plasma Glucose (a)

		Fasting Glucose		Total
		No Diabetes	Diabetes	
HBA1C	No diabetes	306=86.19%	0	306=86.19%
	Diabetes	38=10.70%	11=3.09%	49=13.80%
Total		**344=96.90%**	**11=3.09%**	**355**

a = Post Glucose = No Diabetes

Table-8

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	70.890(b)	1	.000		
Continuity Correction(a)	63.611	1	.000		
Likelihood Ratio	45.900	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	70.691	1	.000		
N of Valid Cases	355				

a Computed only for a 2x2 table, b 1 cells (25.0%) have expected count less than 5.

The minimum expected count is 1.52.c post glucose = no diabetes. Here we find that with PPG criteria≤199mg/dl as not having diabetes, 96.9% and 86.19% tested negative for diabetes with FPG and HbA1C criteria respectively.

Table-9: Fasting Plasma Glucose ≥ 126 mg/dl as a standard for diagnosis of diabetes, compared to Post 75 g glucose at 2 hours ≥200mg/dl.

Test	Present	n	Absent	n	Total
Positive	True Positive	a=80	False Positive	c=57	a + c = 137
Negative	False Negative	b=11	True Negative	d=346	b + d = 357
Total		**a + b = 91**		**c + d = 403**	

Statistic	Value	95% CI
Sensitivity	87.91%	79.40% to 93.81%
Specificity	85.86 %	82.07% to 89.11%
Positive Likelihood Ratio	6.22	4.83 to 8.00
Negative Likelihood Ratio	0.14	0.08 to 0.25
Disease prevalence	18.42% (*)	15.10% to 22.13%
Positive Predictive Value	58.39% (*)	52.16% to 64.37%
Negative Predictive Value	96.92 % (*)	94.75% to 98.21%
Accuracy	86.23% (*)	82.88% to 89.15%

Table-10: Post 75 g glucose (PPG) =200 mg/dl DM as a standard for diagnosis compared to FPG

Test	Present	n	Absent	n	Total
Positive	True Positive	a=81	False Positive	c=11	a + c = 92
Negative	False Negative	b=57	True Negative	d=347	b + d = 404
Total		**a + b = 138**		**c + d = 358**	

Table-1

Statistic	Value	95% CI
Sensitivity	58.70%	50.01% to 67.00%
Specificity	96.93 %	94.57% to 98.46%
Positive Likelihood Ratio	19.10	10.50 to 34.75
Negative Likelihood Ratio	0.43	0.35 to 0.52
Disease prevalence	27.82% (*)	23.92% to 31.99%
Positive Predictive Value	88.04% (*)	80.19% to 93.05%
Negative Predictive Value	85.89 % (*)	83.29% to 88.14%
Accuracy	86.29% (*)	82.95% to 89.19%

Table-2: Hba1c≥6.5% as standard compared to PPG

Test	Present	n	Absent	n	Total
Positive	True Positive	a=108	False Positive	c=29	a + c = 137
Negative	False Negative	b=49	True Negative	d=306	b + d = 355
Total		**a + b = 157**		**c + d = 335**	

Table-3

Statistic	Value	95% CI
Sensitivity	68.79%	60.92% to 75.94%
Specificity	91.34 %	87.80% to 94.13%
Positive Likelihood Ratio	7.95	5.52 to 11.43
Negative Likelihood Ratio	0.34	0.27 to 0.43
Disease prevalence	31.91% (*)	27.81% to 36.23%
Positive Predictive Value	78.83% (*)	72.14% to 84.27%
Negative Predictive Value	86.20 % (*)	83.16% to 88.76%
Accuracy	84.15% (*)	80.61% to 87.26%

Table-4: HbA1C≥6.5% as standard vs FPG

Test	Present	n	Absent	n	Total
Positive	True Positive	a=88	False Positive	c=3	a + c =91
Negative	False Negative	b=69	True Negative	d=335	b + d =404
Total		**a + b = 157**		**c + d = 338**	

Table-5

Statistic	Value	95% CI
Sensitivity	56.05%	47.92% to 63.95%
Specificity	99.11 %	97.43% to 99.82%
Positive Likelihood Ratio	63.15	20.30 to 196.48
Negative Likelihood Ratio	0.44	0.37 to 0.53
Disease prevalence	31.72% (*)	27.64% to 36.02%
Positive Predictive Value	96.70% (*)	90.41% to 98.92%
Negative Predictive Value	82.92 % (*)	80.27% to 85.28%
Accuracy	85.45% (*)	82.04% to 88.44%

Table-6: PPG≥200mg/dl as a standard vs HBA1C

	Disease				
Test	**Present**	**n**	**Absent**	**n**	**Total**
Positive	True Positive	a=109	False Positive	c=49	a + c = 158
Negative	False Negative	b=29	True Negative	d=308	b + d = 337
Total		**a + b = 138**		**c + d = 357**	

Table-7

Statistic	**Value**	**95% CI**
Sensitivity	78.99%	71.23% to 85.45%
Specificity	86.27 %	82.26% to 89.67%
Positive Likelihood Ratio	5.75	4.38 to 7.57
Negative Likelihood Ratio	0.24	0.18 to 0.34
Disease prevalence	27.88% (*)	23.97% to 32.05%
Positive Predictive Value	68.99% (*)	62.85% to 74.53%
Negative Predictive Value	91.39 % (*)	88.46% to 93.64%
Accuracy	84.24% (*)	80.73% to 87.34%

Table-8: FPG≥126 mg/dl as a standard vs Hba1c

Disease					
Test	**Present**	**n**	**Absent**	**n**	**Total**
Positive	True Positive	a=88	False Positive	c=69	a + c = 157
Negative	False Negative	b=3	True Negative	d=335	b + d = 338
Total		**a + b = 91**		**c + d = 404**	

Table-9

Statistic	**Value**	**95% CI**
Sensitivity	96.70%	90.67% to 99.31%
Specificity	82.92 %	78.89% to 86.46%
Positive Likelihood Ratio	5.66	4.55 to 7.04
Negative Likelihood Ratio	0.04	0.01 to 0.12
Disease prevalence	18.38% (*)	15.07% to 22.08%
Positive Predictive Value	56.05% (*)	50.63% to 61.34%
Negative Predictive Value	99.11 % (*)	97.35% to 99.71%
Accuracy	85.45% (*)	82.04% to 88.44%

Conclusion

Our study shows that HbA1C correlates well with FPG unlike PPG. The sensitivity of the test is comparable at and can be used along with plasma glucose level estimation but is cannot be replaced for plasma glucose estimation. Cost and standardisation of HbA1C assays is a big hurdle in the Indian context. Hba1c and PPG if negative almost rules out diabetes, as the specificity is very high.

While screening a population these two tests can be combined in one test to rule out diabetes and additional testing can be scheduled at a longer interval.

If a single test needs to be used a post glucose or a post prandial glucose levels are more relevant for our population as we may miss 42% of them with only a FPG level.

Also the sensitivity and specificity of the HbA1C is similar to Fasting plasma glucose estimates. Hence whether PPG and HbA1c can be combined in a single test to diagnose diabetes. Blood glucose estimation are easily available even in primary health centres, but subjecting people to a fasting test and glucose challenge can be cumbersome.

If a single blood test at any time of the day could diagnose diabetes it may be worthwhile as we may prevent long term complications and its morbidity. AnHbA1C test candiagnose diabetes at any time of the day and be convenient.

It is not affected by erythrocyte turnover and can be used in patients with dyslipi-daemias, hepatic, renal or thyroid dysfunction. My co-authors Dr Surekha Shetty contributed to the study data and manuscript preparation. Dr Anil Kumar contributed to data and statistical analyses.

Study inferences for our population: From our study we find that a higher number of subjects fit the post glucose criteria than fasting glucose criteria hence a post prandial or post glucose challenge is compulsory to identify at risk individuals.

Our population have a specific Asian phenotype which puts them at a risk for developing cardiovascular risks compared to other races. In our study we find that 42% of the people meeting the PPG criteria are missed with the FPG criteria.

As the sensitivity of HbAIC is high in people with higher Fasting glucose levels, a Fasting glucose is not absolutely necessary.

If a combination of tests in a single sample can diagnose diabetes accurately in all populations, an ideal diagnostic test would be available. Further studies may be required to look into the feasibility of developing a single test with standardised criteria and develop newer assays apart from HbA1C.

Funding: Nil, **Conflict of interest:** None
Permission of IRB: Yes

References

1. International Diabetes Federation. IDF Diabetes Atlas, 8th edn. Brussels, Belgium: International Diabetes Federation, 2017.

2. American Diabetes Association. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018 Jan;41(Suppl 1):S13-S27. doi: 10.2337/dc18-S002.

3. Adepoyibi T, Weigl B, Greb H, Neogi T, McGuire H. New screening technologies for type 2 diabetes mellitus appropriate for use in tuberculosis patients. Public Health Action. 2013 Nov 4;3(1):10-7.

4. International Expert Committee. International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care. 2009 Jul;32 (7):1327-34. doi: 10.2337/dc09-9033. Epub 2009 Jun 5.

5. American Diabetes Association. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018 Jan;41(Suppl 1): S13-S27. doi: 10.2337/dc18-S002.

6. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia: report of a WHO / IDF consultation. 2006 IDF Consultation. Geneva, World Health Org., 2006

7. Gallagher EJ, Le Roith D, Bloomgarden Z. Review of hemoglobin A(1c) in the management of diabetes. J Diabetes. 2009 Mar;1(1): 9-17. doi: 10.1111/j.1753-0407. 2009. 00009.x. Epub 2009 Jan 27.

8. Ziemer DC, Kolm P, Weintraub WS, et al. Glucose-independent, black-white differences in hemoglobin A1c levels: a cross-sectional analysis of 2 studies. Ann Intern Med. 2010 Jun 15;152(12):770-7. doi: 10.7326/ 0003-4819-152-12-201006150-00004.

9. Kumar PR, Bhansali A, Ravikiran M, et al. Utility of glycated hemoglobin in diagnosing type 2 diabetes mellitus: a community-based study. J Clin Endocrinol Metab. 2010 Jun;95 (6): 2832-5. doi: 10.1210/jc. 2009-2433. Epub 2010 Apr 6.

10. Bonora E, Tuomilehto J. The pros and cons of diagnosing diabetes with A1C. Diabetes Care. 2011 May;34 Suppl 2:S184-90. doi: 10.2337/dc11-s216.

11. Mohanty D, Colah RB, Gorakshakar AC, et al. Prevalence of β-thalassemia and other haemoglo-binopathies in six cities in India: a multicentre study. J Community Genet. 2013 Jan;4 (1):33-42. doi: 10.100 7 / s12687-012-0114-0. Epub 2012 Oct 21.

12. Cowie CC, Rust KF, Byrd-Holt DD, et al. Prevalence of diabetes and high risk for diabetes using A1C criteria in the U.S. population in 1988-2006. Diabetes Care. 2010 Mar;33(3):562-8. doi: 10.2337/ dc09-1524. Epub 2010 Jan 12.

13. Wang W, Lee ET, Howard BV, et al. Fasting plasma glucose and hemoglobin A1c in identifying and predicting diabetes: the strong heart study. Diabetes Care. 2011 Feb;34(2):363-8. doi: 10.2337/dc10-1680.

14. Yun WJ, Shin MH, Kweon SS, Park KS, Lee YH, Nam HS, Jeong SK, Yun YW, Choi JS. A comparison of fasting glucose and HbA1c for the diagnosis of diabetes mellitus among Korean adults. Journal of preventive medicine and public health. 2010 Sep;43(5):451-4.

15. van 't Riet E, Alssema M, Rijkelijkhuizen JM, et al. Relationship between A1C and glucose levels in the general Dutch population: the new Hoorn study. Diabetes Care. 2010 Jan;33(1):61-6. doi: 10.2337/dc09-0677. Epub 2009 Oct 6.

16. Rohlfing CL, Wiedmeyer HM, Little RR, et al. Defining the relationship between plasma glucose and HbA(1c): analysis of glucose profiles and HbA(1c) in the Diabetes Control and Complications Trial. Diabetes Care. 2002 Feb;25(2):275-8.

17 Kavya S. T, Nagaraja B. S, Akila V, G. Chandra Mohan, Prakash KikkerGowdaiah. Comparative Study of Glycosylated Haemoglobin with Blood Glucose Levels in the Diagnosis of Diabetes Mellitus. Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 23, June 09; Page: 6435-6443, DOI: 10.14260/ jemds/2014/2760

How to cite this article?

Lalitha R., Shetty S.B., Anil Kumar R. A study to evaluate HbA1C as an independent diagnostic criterion comparing to fasting plasma glucose and postprandial glucose levels as a standard test for diagnosis of diabetes. *Int J Med Res Rev* 2018; 6(08): 493-502. doi:10.17511/ijmrr.2018.i08.15.

……..