International Journal of Research in Medical Sciences
Khandhedia P et al. Int J Res Med Sci. 2022 Apr;10(4):850-861
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20220976

Original Research Article

Significance of diagnostic and monitoring criterion of HbA1c as compared with fasting and 2-hour plasma glucose concentration in GCS general hospital, Ahmedabad: a retrospective study

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Received: 07 January 2022
Revised: 04 February 2022
Accepted: 07 February 2022

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ABSTRACT

Background: Diabetes is a chronic disorder that has reached epidemic levels. Its complications are potentially life-threatening but can be slowed by early diagnosis and treatment. Complications develop earlier in patients having more fluctuating levels of blood glucose than those having maintained levels. Early diagnosis and treatment confer more benefits than aggressive control.
Methods: As it was a retrospective study; the data was collected from available records of patients in whom all the three tests have been executed and analysed using SPSS version 26.
Results: Diabetics were 199 (53.9%) based on FPG (fasting plasma glucose); 169 (45.8%) based on 2hPG (2-hour plasma glucose) and 230 (62.3%) based on HbA1c. When diagnosed with FPG, the sensitivity and specificity of HbA1c was 89.44% and 69.41% respectively, whereas with 2hPG it was 92.89% and 63.5%. When HbA1c was compared with FPG and 2hPG, the values are affected with history of diastolic hypertension and family history of diabetics. The values correlated with that of FPG as well as 2hPG and showed linear relationship. The regression equation HbA1c (%)=3.737+0.027×FPG (mg/dl) explains 50.4% of variation and with less error when compared to 2hPG. Hence, the values of FPG can be used to predict the approximate values of HbA1c through regression.
Conclusions: Study revealed that HbA1c has a greater potential as a diagnostic test due to its high sensitivity. The levels are affected by family history and diastolic hypertension. Our study suggests that diagnosing criteria of diabetes should be HbA1c ≥7.1% instead of the current criteria of HbA1c ≥6.5% by the relationship of HbA1c with FPG.

Keywords: HbA1c, Fasting plasma glucose, 2-hour plasma glucose, Diabetes

INTRODUCTION

Diabetes is one of the most common chronic disorders that has reached epidemic levels in whole world.[1] In India, a recent study showed that total annual expenditure by patients on diabetes care had risen from INR 4,200 (USD 95) to INR 9,000 (USD 203) between 1998 to 2005. The indirect cost is more difficult to assess and is much higher than the direct cost. The proportion of annual income spent on health care is about 25% to 30% by the poor people. The cost increases many folds when diabetic complications are present.[2]

Earlier, it was considered to be the disease of the affluent society. However, it has now spread to each and every community of the world. Undiagnosed population is estimated to be Seven million people, and a large percentage of newly diagnosed already have complications at the time of diagnosis.

Diabetes and its complications are serious and potentially life-threatening, but the disease process can be halted or slowed by effective treatment. Studies suggest that early diagnosis and proper treatment confer more health benefits than the aggressive control of other comorbidities after the diagnosis of the diabetes.[3] Additionally, delaying the screening increases the risk of other comorbidities. Thus, proper early screening and diagnostic methods are required to identify people at risk. Thus HbA1c, a simple diagnostic test has been suggested by various organisations.

A nonenzymatic reaction occurs between glucose and haemoglobin which was characterised in 1968 that produces HbA1c.[4] Rahbar et al in 1969 reported elevation of HbA1c in diabetic patients.[5] The fraction of HbA1c increases as plasma glucose levels increases in a predictable way. It indicated the average blood glucose levels over the previous months prior to the measurement. Subsequently in 1976, the clinical application of HbA1c to monitor glycaemic control was demonstrated.[6] Since then, it has become a standard in the care of diabetic patients for monitoring control over a 3-month period.

A reduction in HbA1c demonstrated aggressive improvement in glycaemic control and reduced the rate of complications and improved quality of life.[7] However, due to lack of standardization, HbA1c was not incorporated as a diagnostic tool till 2009.[8]

The American diabetes association in 2010 included HbA1c ≥6.5% (48 mmol/mol) as a diagnostic criterion based on its correlation with retinopathy.[8] Only one longitudinal study since then has validated the inflection point of HbA1c ≥6.5% (48 mmol/mol) for increased incidence of retinopathy and other longitudinal studies have suggested that the inflection point for retinopathy may not be at HbA1c of 6.5% (48 mmol/mol).[9-13]

Thus, HbA1c ≥6.5% (48 mmol/mol) has not been validated as the inflection point at which the risk of retinopathy increases.[14] And hence, the current diagnostic cut-off for diabetes based on HbA1c is in a quandary and it is highly likely that it will be revised in the future.

Diabetes is characterised by hyperglycaemia resulting from defects in insulin secretion, insulin action or both.[15] However, many a times hyperglycaemia is confused as the risk factor of the disease. A patient is said to be diabetic if there is increased level of glucose in the blood. It is diagnosed by various methods such as FBG, 2hPG, glucose tolerance test and glycated haemoglobin levels. Diabetes is diagnosed by FPG ≥126 mg/dl (7.0 mmol/l) or a 2hPG level ≥200 mg/dl (11.1 mmol/l).[16,17] In 2009, HbA1c ≥6.5% (48 mmol/mol) was defined as one of the diagnostic criteria for diabetes.[18]

However, any single parameter cannot be relied upon for the diagnosis. The various tests show the glucose levels at different times. Some tests show instantaneous glucose levels and some over a period of last 3 months. There is the continuous variation in the level of blood glucose according to the intake of food by person and the action of insulin. Hence, any single parameter if used for the diagnosis and monitoring may lead the patient to risk of complications due to either over-treatment or under-treatment both of which are harmful. The complications develop early in patients who have more fluctuating levels of blood glucose than those who have maintained levels.[19]

Our study examined the efficacy of using HbA1c in diagnosing and monitoring diabetes compared to FPG and 2hPG. Also, it investigated the sensitivity and specificity of current diagnostic and monitoring criterion for diabetes to facilitate the early diagnosis and effective management.

Aims and objectives

The aims and objectives were to evaluate the validity of HbA1c for diagnosing diabetes on the study subjects already being diagnosed by FPG and 2hPG; to correlate the HbA1c levels with that of the FBG as well as 2hPG levels; to find out the association between HbA1C and known risk factors for diabetes in study subjects on the grounds on FPG and 2hPG; to assess the dependability of HbA1c ≥6.5% (48 mmol/mol) as a diagnostic test for diabetes.

METHODS

It was a retrospective study conducted in GCS general hospital, Ahmedabad. Data was obtained from biochemistry laboratory regarding the tests done during last 4 years, that was, 1 January 2016 to 31 December 2019 in the previous indoor patients. During the last 4 years total 4,43,562 patients visited GCS hospital out of which 39,856 were the indoor patients. And in only 23,016 patients various glucose tests were caried out. Patients in whom all the 3 tests were done, HbA1c, FBG as well as 2hPG, 414 patients were selected. However, 369 were selected as study participants as in others either records were not available or incomplete records were present.

Inclusion criteria

Patients with more than 18 years of age; patients in whom all the 3 tests, HbA1c, FBG and 2hPG have been carried out; patients who have been admitted in the hospital were included in the study.

Exclusion criteria

Patients below 18 years of age; patients in whom all the three tests have not been carried out; patients in whom tests were carried out in OPD basis were excluded.

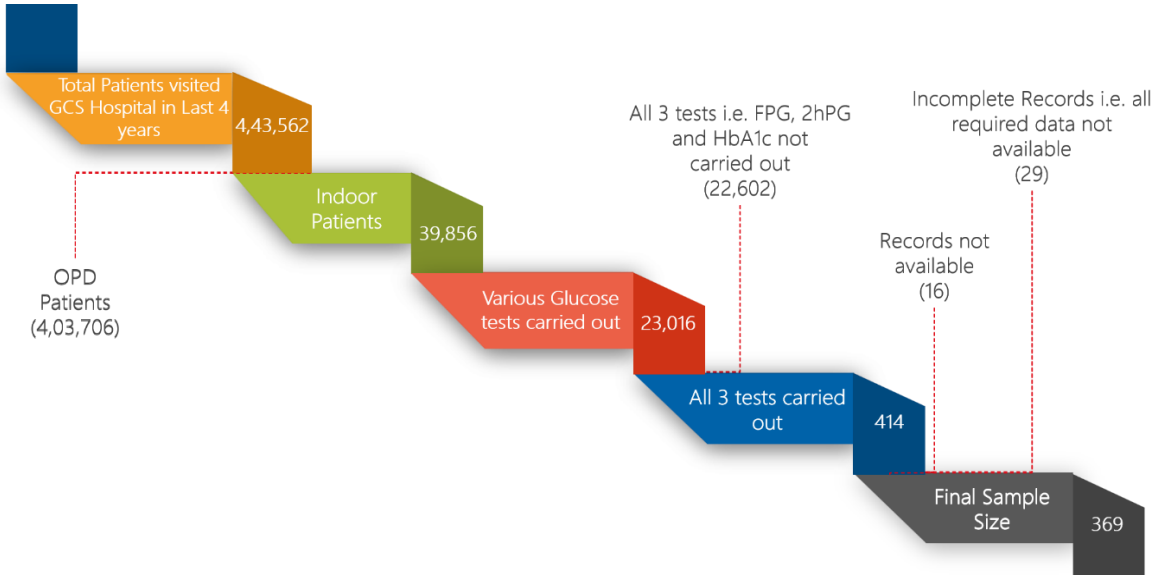

Figure 1: Selection of study participants.

Period of study

The period of study was February 2020 to March 2020.

A standard pre-evaluated proforma was designed to obtain information from the available records. It consisted of sociodemographic data; personal history (addiction); family history and other co-existing medical history.

Height, weight as well as blood pressure was noted from the hospital records and analysed accordingly. The information was recorded by the investigator directly in google forms and the data was exported to the excel sheet and analysed by suitable statistical tests for the significance by using SPSS version 26 and MS-excel.

Diagnostic criteria of diabetes

For this study, in accordance with the guidelines set forth by the American diabetes association, diabetes was defined as having a FPG ≥126 mg/dl (7.0 mmol/l), 2hPG ≥200 mg/dl (11.1 mmol/l) or HbA1c ≥6.5% (48 mmol/mol).[16-18]

Laboratory methods

HbA1c: HbA1c was measured using Bio-Rad D10 HPLC based Glycohemoglobin analyzer.

Plasma glucose: Plasma glucose concentration were determined by GOD-POD method which was an endpoint enzymatic method using a sample blank correction. A fasting blood test was performed on all participants 18 years old and older; to be examined in the morning session, following a 9-hour fast. After the initial venepuncture, a second venepuncture was performed 2-hour (±15 minutes) post prandial.

RESULTS

Study population

The clinical characteristics of 369 subjects in this study are shown in Table 1. The COHORT had a mean age of 51 years and a mean BMI of 28.49 kg/m^2. Based on the established diagnostic criteria, 230 (62.3%) subjects were diabetic with HbA1c, ≥6.5%, 199 (53.9%) subjects were diabetic with FPG ≥126 mg/dl and 169 (45.8%) subjects were diabetic with 2hPG ≥200 mg/dl (Table 1).

Diabetics based on FPG versus HbA1c

Among 199 individuals that had FPG ≥126 mg/dl, 178 had HbA1c ≥6.5% and 21 had HbA1c <6.5% (Table 2). The sensitivity and specificity of HbA1c ≥6.5% in diagnosing diabetes mellitus based on FPG ≥126 mg/dl were 89.44% and 69.41% respectively. The positive predictive value (PPV) and the negative predictive value (NPV) were 77.39% and 84.89% respectively.

Subjects that met the criteria for diagnosis of diabetes mellitus based on FPG ≥126mg/dl were further analysed in two groups based on HbA1c <6.5% versus ≥6.5% (Table 3). There were no statistically significant differences between the two groups in regard to age, gender, occupation, smoking, alcohol consumption and BMI. However, family history of diabetes (p=0.026) and diastolic blood pressure (p=0.001) approached significance because more subjects from the group HbA1c ≥6.5% had family history and higher diastolic blood pressure.

Table 1: Clinical features of the studied subjects (n=369).

Clinical features	Frequency (%) N (%)	Mean	SD	Median
Age (years)				
18-30	34 (9.2)	51.32	15.09	53
31-40	57 (15.4)			
41-50	77 (20.9)			
51-60	92 (24.9)			
61-70	80 (21.7)			
>70	29 (7.9)			
Gender				
Male	188 (50.9)			
Female	181 (49.1)			
Occupation				
Working	121 (32.8)			
Not working	248 (67.2)			
Smoking, yes	89 (24.1)			
Alcohol, yes	62 (16.8)			
Family history of diabetes, yes	132 (35.8)			
BMI (kg/m^2)				
Underweight	3 (0.8)	28.49	5.00	27.39
Normal	83 (22.5)			
Overweight	159 (43.1)			
Obese	124 (33.6)			
Systolic blood pressure (mmHg)				
≥130	169 (45.8)	130	14	126
Diastolic blood pressure (mmHg)				
≥90	103 (27.9)	83	9	83
HbA1c (%)				
HbA1c ≥ 6.5	230 (62.3)	7.6	2.4	7.4
FPG (mg/dl)				
FPG ≥126	199 (53.9)	148	64	134
2hPG (mg/dl)				
2hPG ≥200	169 (45.8)	209	97	188

Table 2: Subjects meeting diagnostic criteria of diabetes by FPG ≥126mg/dl.

Parameters		Diabetes by FPG		
		Present, ≥126 mg/dl	Absent, <126 mg/dl	Total
HbA1c	Positive, ≥6.5%	178	52	230
	Negative, <6.5%	21	118	139
Total		199	170	369

Table 3: Clinical features of subjects with FPG ≥126mg/dl (n=199).

Clinical features	HbA1c ≥6.5%	HbA1c <6.5%	Total (%)	χ^2	P
Age (years)			52.75±13.62		
18-30	8	0	8 (4)		
31-40	25	4	29 (14.6)		
41-50	45	3	48 (24.1)	3.658	0.574
51-60	48	7	55 (27.6)		
61-70	40	4	44 (22.1)		
>70	12	3	15 (7.5)		
Gender					

Continued.

Clinical features	HbA1c ≥6.5%	HbA1c <6.5%	Total (%)	χ^2	P
Male	101	14	115 (57.8)	0.759	0.384
Female	77	7	84 (42.2)		
Occupation, working	57	10	67 (33.7)	2.046	0.153
Smoking, yes	44	9	53 (26.6)	3.163	0.075
Alcohol, yes	29	6	35 (17.6)	1.954	0.162
Family History of Diabetes, yes	58	12	70 (35.2)	4.968	0.026
BMI, kg/m^2			28.71±5.11		
Underweight	2	0	2 (1)	1.807	0.580
Normal	33	6	39 (19.6)		
Overweight	75	9	84 (42.2)		
Obese	68	6	74 (37.2)		
Systolic blood pressure (mmHg)			131±14		
≥130	81	10	91 (45.7)	0.034	0.854
Diastolic blood pressure (mmHg)			83±9		
≥90	43	12	55 (27.6)	10.219	0.001

Table 4: Subjects meeting diagnostic criteria of diabetes by 2hPG ≥200mg/dl.

Parameters		Diabetes by 2hPG		
		Present, ≥200 mg/dl	Absent, <200 mg/dl	Total
HbA1c	Positive, ≥6.5%	157	73	230
	Negative, <6.5%	12	127	139
Total		169	200	369

Table 5: Clinical features of subjects with 2hPG ≥200 mg/dl (n=169).

Clinical features	HbA1c ≥6.5%	HbA1c <6.5%	Total (%) mean±SD	χ^2	P
Age (years)			52.30±12.89		
18-30	7	0	7 (4.1)	Fisher's exact=8.536	0.079
31-40	20	0	20 (11.8)		
41-50	45	2	47 (27.8)		
51-60	45	5	50 (29.6)		
61-70	34	2	36 (21.3)		
>70	6	3	9 (5.3)		
Gender					
Male	85	6	91 (53.8)	0.77	0.782
Female	72	6	78 (46.2)		
Occupation, working	52	4	56 (33.1)	Yate's χ^2=0.092	0.761
Smoking, yes	38	4	42 (24.9)	Yate's χ^2=0.129	0.719
Alcohol, yes	25	3	28 (16.6)	Yate's χ^2=0.17	0.680
Family history of diabetes, yes	47	8	55 (32.5)	Yate's χ^2=5.28	0.021
BMI, kg/m^2			28.91±5.02		
Underweight	1	0	1 (0.6)	Fisher's exact=1.541	0.870
Normal	30	3	33 (19.5)		
Overweight	64	5	69 (40.8)		
Obese	62	4	66 (39.1)		
Systolic blood pressure, mmHg			131±14		
≥130	73	7	80 (47.3)	0.627	0.429
Diastolic blood pressure, mmHg			82±9		
≥90	36	7	43 (25.4)	7.366	0.007

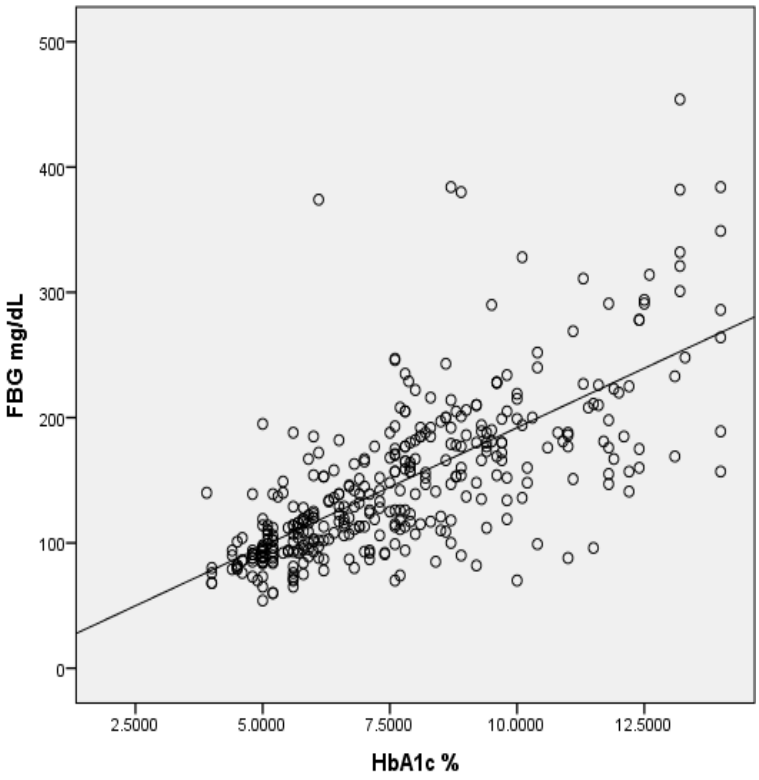

Figure 2: Scatter diagram of correlation between HbA1c and FPG.

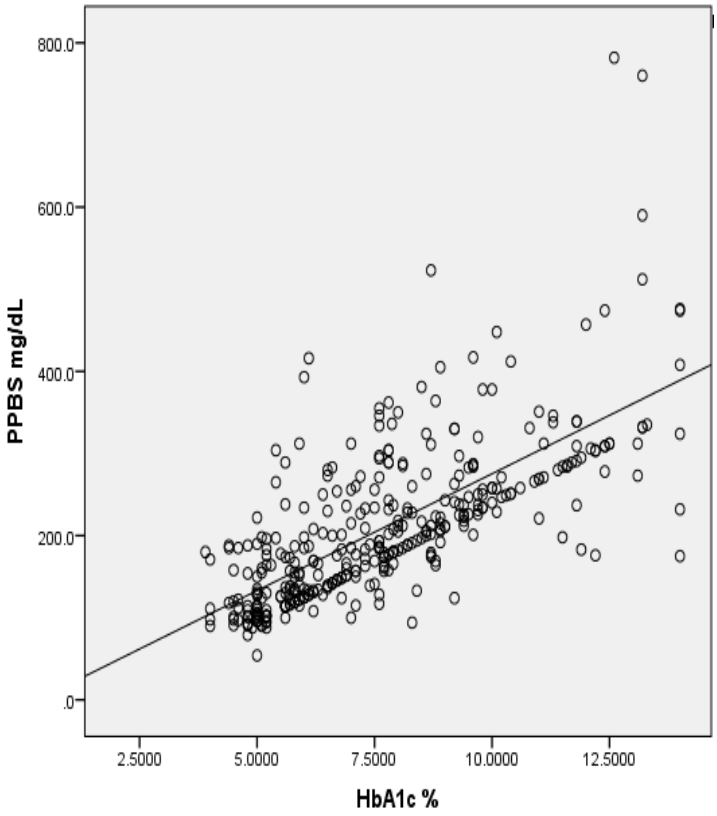

Figure 3: Scatter diagram of correlation between HbA1c and 2hPG.

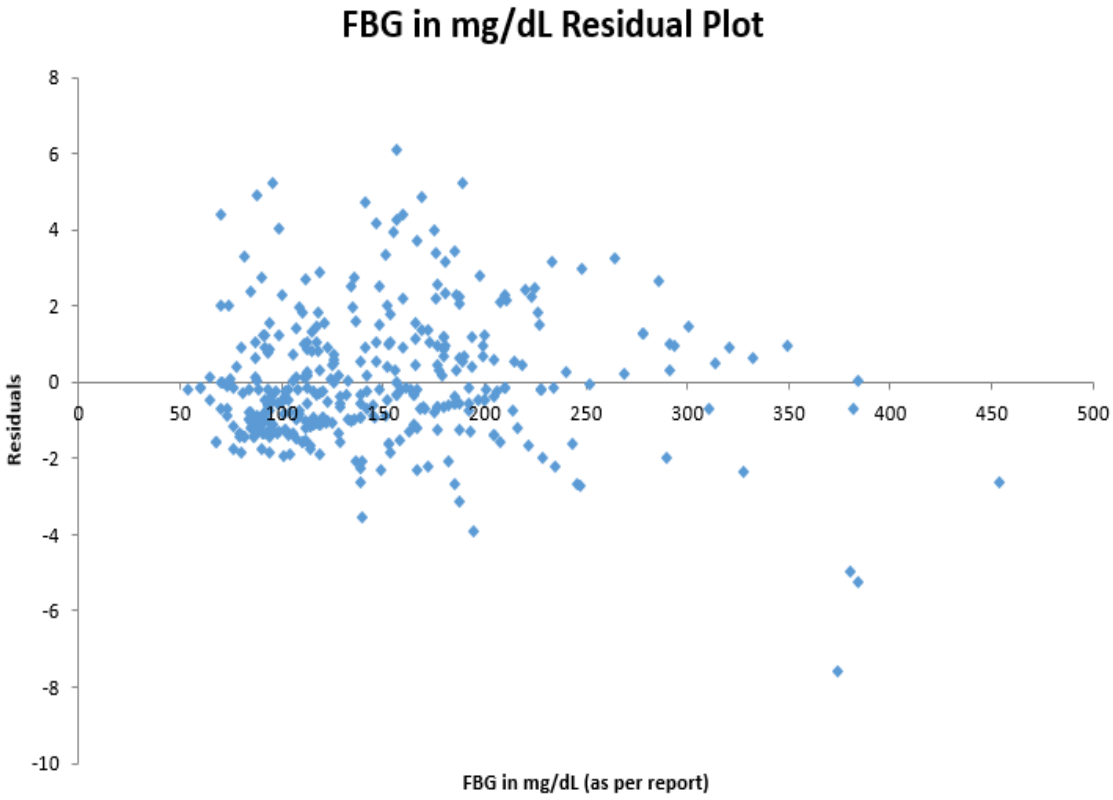

Figure 4: HbA1c and FPG regression residual plot.

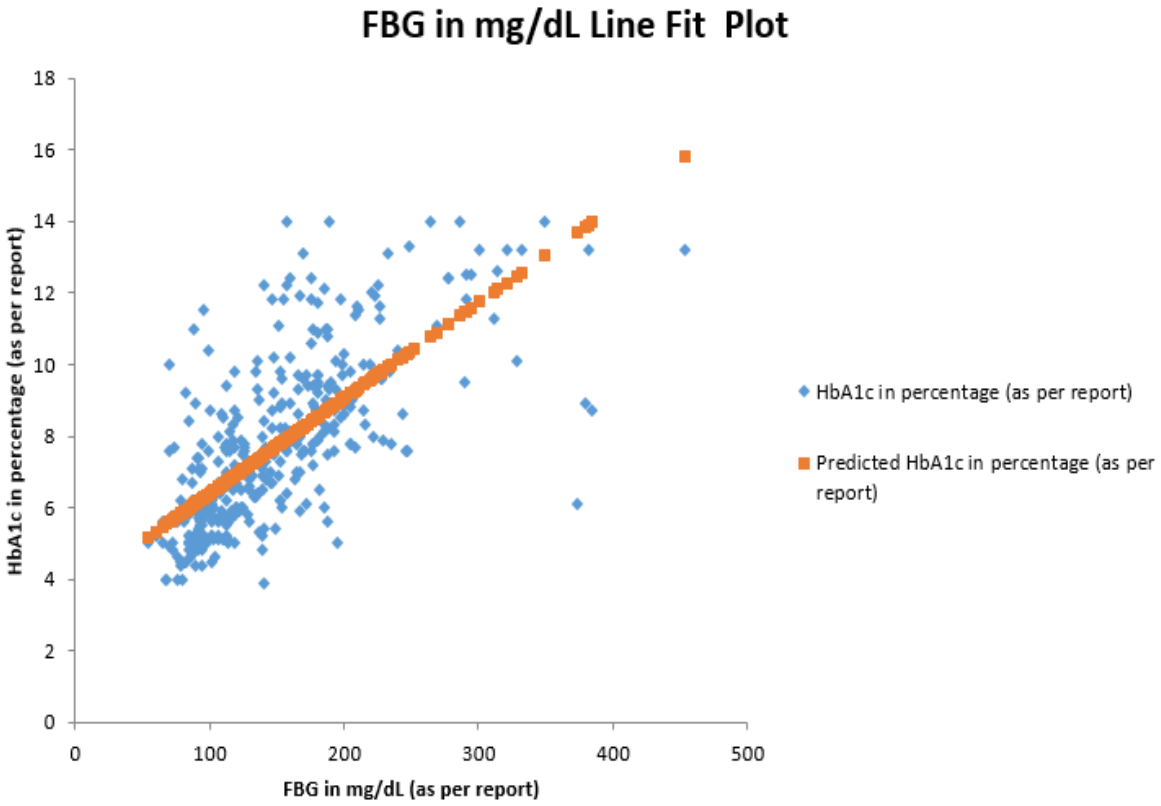

Figure 5: HbA1c and FPG regression line fit plot.

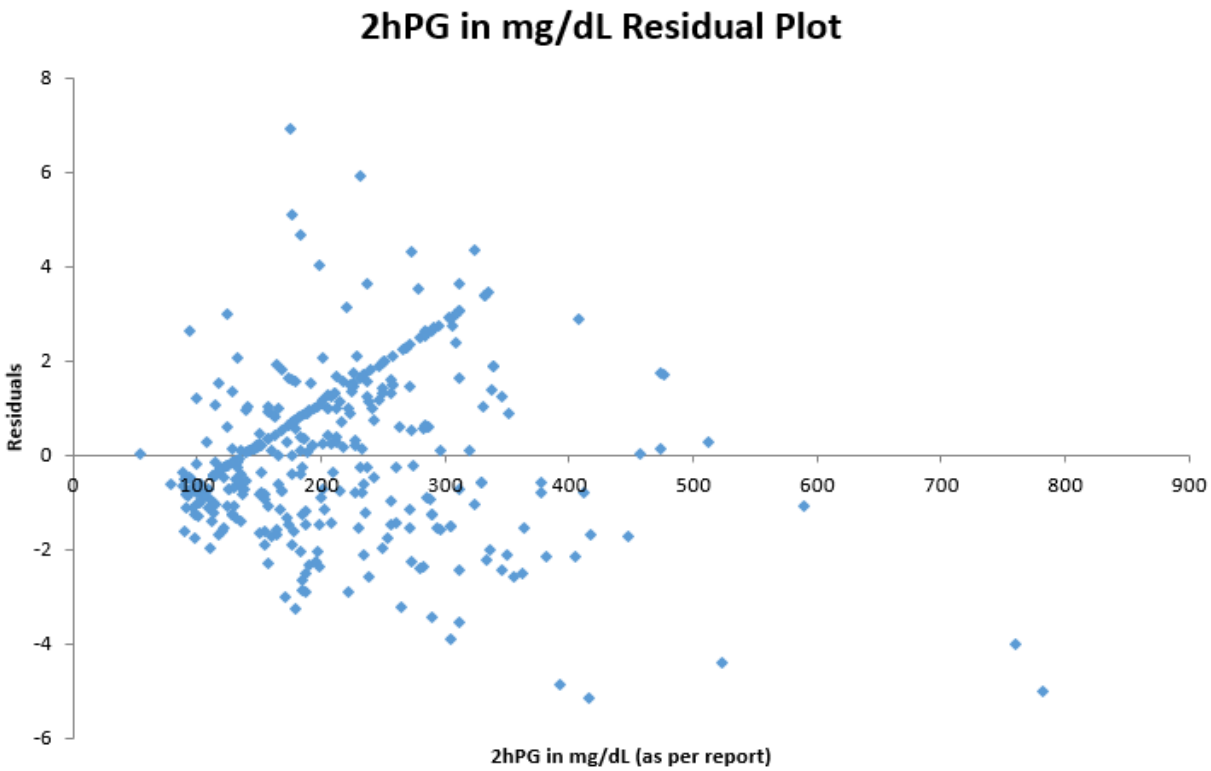

Figure 6: HbA1c and 2hPG regression residual plot.

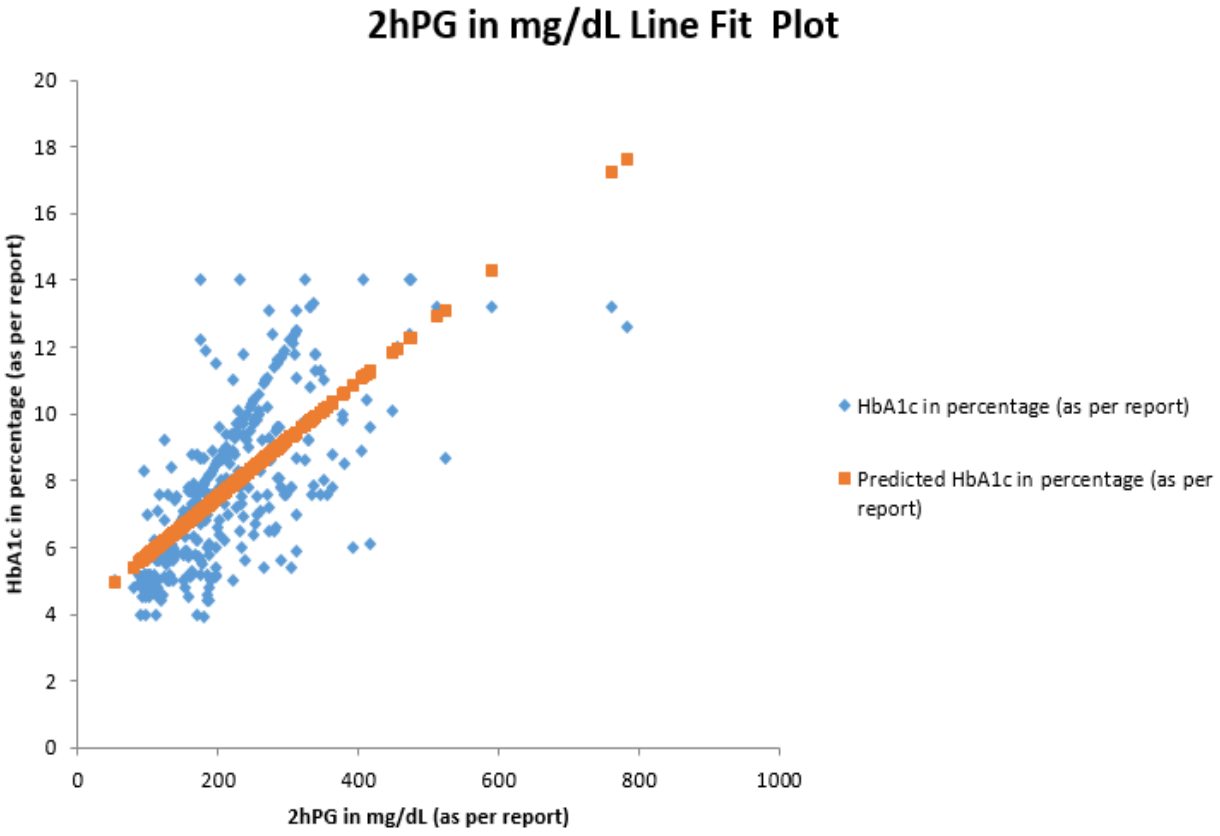

Figure 7: HbA1c and 2hPG regression line fit plot.

Diabetics based on 2hPG versus HbA1c

Among 169 individuals that had 2hPG ≥200 mg/dl, 157 had HbA1c, ≥6.5% and 12 had HbA1c <6.5% (Table 4). The sensitivity and specificity of HbA1c ≥6.5% in diagnosing diabetes mellitus based on 2hPG ≥200 mg/dl were 92.89% and 63.50% respectively. The PPV and the NPV were 68.26% and 91.36% respectively.

Subjects that met the criteria for diagnosis of diabetes mellitus based on 2hPG ≥200mg/dl were further analysed in two groups based on HbA1c <6.5% versus ≥6.5% (Table 5). There were no statistically significant differences between the two groups in regard to age, gender, occupation, smoking, alcohol consumption and BMI. Family history of diabetes (p=0.021) and diastolic blood pressure (p=0.007) approached significance because more subjects from the group HbA1c ≥6.5% had family history and higher diastolic blood pressure.

Correlation tests

Correlation between HbA1c and FPG

Karl Pearson's correlation coefficient was 0.711. As p<0.05, we rejected the null hypothesis. We concluded that there existed a positive correlation between the values of HbA1c and FPG. As the correlation coefficient r was between 0.5 and 1, it showed there was a strong positive relationship.

Correlation between HbA1c and 2hPG

Karl Pearson's correlation coefficient was 0.702. As p<0.05, we rejected the null hypothesis. We concluded that there existed a positive correlation between the values of HbA1c and 2hPG. As the correlation coefficient r was between 0.5 and 1, it showed there was a strong positive relationship.

Regression between HbA1c and FPG

It was used to find out an equivalent HbA1c value in respect to FPG. The value of the slope of the coefficient β was 0.027 and it was significant as p<0.05. The null hypothesis was rejected and we can conclude that the two variables were linearly related with each other. The linear relationship was defined by,

HbA1c (%)=$\mathbf{3.737 + 0.027 \times \boldsymbol{FPG}}$.

The F ratio was 374.302 and p<0.05 and hence the null hypothesis was rejected. We can conclude that our regression variable fits the data well. The value of coefficient of determination was 0.505 hence, 50.5% of variation was well explained by our model and the rest was because of the randomness.

Regression between HbA1c and 2hPG

It was used to find out an equivalent HbA1c value in respect to 2hPG. The value of the slope of the coefficient β was 0.017 and it was significant as p<0.05. The null hypothesis was rejected and we can conclude that the two variables were linearly related with each other. The linear relationship was defined by,

HbA1c (%)=4.050+0.017×2hPG (mg/dl).

The F ratio was 357.167 and p<0.05 and hence the null hypothesis was rejected. We can conclude that our regression variable fits the data well. The value of coefficient of determination was 0.493 hence, 49.3% of variation was well explained by our model and the rest was because of the randomness.

The predicted values of HbA1c by FPG had lesser residual error, high coefficient of determination and less standard error of estimate when compared to the predicted values by 2hPG. Hence, the values of the HbA1c are better predicted with the FPG then 2hPG.

If the value of FPG was ≥126 mg/dl, the patient was said to have suffering from diabetes. Based on linear relationship explained by FPG model,

HbA1c (%)=3.737+0.027×FPG (mg/dl),

a FPG of 126 mg/dl correlated closer to HbA1c of 7.1%. Hence, if the FPG model was taken as standard the diagnostic criteria of the diabetes by HbA1c should be HbA1c ≥7.1% instead of the current criteria of HbA1c ≥6.5%.

DISCUSSION

The present study was conducted to explore the agreement between plasma glucose (either FPG or 2hPG) and HbA1c to diagnose diabetes and to measure the accuracy of using HbA1c ≥6.5% as a diagnostic tool. We obtained our data from 2016-2019 medical records and found that, of the 199 subjects that had FPG ≥126mg/dl, 178 subjects (89.4%) had HbA1c ≥6.5% and specificity of 69.4%. Out of 169 subjects who had 2hPG ≥200mg/dl, 157 subjects (92.8%) had HbA1c ≥6.5% and specificity of 63.5%. The specificity of the HbA1c criterion in diagnosing diabetes suggested that using an HbA1c ≥6.5% as a criterion for diagnosing diabetes will likely lead to some of missed diagnoses.

The HbA1c levels in recent years had been included as a diagnostic criterion for diabetes. Previously, it was used as a marker of glycaemic control, because it reflected average blood glucose levels over a period of 2 to 3 months. The threshold of HbA1c ≥6.5% as a diagnostic tool was based on the inflection point for the prevalence of retinopathy.[8] Some studies have however shown the poor concordance between HbA1c and FPG or 2hPG

during an OGTT, the most widely accepted diagnostic glucose-based tests.[20,21]

The Rancho Bernardo cross-sectional study which was conducted without the known history of diabetes, showed sensitivity and specificity of HbA1c ≥6.5% against OGTT to be only 44% and 79%, respectively.[20,21] Fajans et al compared the results of HbA1c with FPG of 147 subjects and found that HbA1c <5.7% (39 mmol/mol) was reported amongst one-third of subjects with early diabetes and impaired glucose tolerance (IGT).[20,21]

Nevertheless, because of its practicality and convenience HbA1c remained a recommended diagnostic tool based on the cross-sectional observation studies.[8] There was a benefit conferred to HbA1c when compared with FPG as there was stronger correlation with retinopathy and less variability in day to day within person variance, (<2% for HbA1c versus 12-15% for FPG).[22,23]

It was advocated to diagnosed diabetes on HbA1C ≥6.5% criteria, but a few studies had compared the sensitivity and specificity of HbA1c with 2hPG and 2hPG performed better than HbA1c in classifying diabetes in only one study which was not in respect to the retinopathy but the cardiovascular complications.[24] Among the Asian Americans, the sensitivity of HbA1c ≥6.5% to define diabetes was 40.0% by 2hPG and 68.9% by FPG which was very low as compared to our results.[25] A low sensitivity of HbA1c was shown by several small studies in comparison with OGTT.[21,26-28] However, their observations were not consistent with our results that an HbA1c ≥6.5% had a low specificity in diagnosing diabetes in comparison to FPG and 2hPG.

In reference to FPG, our study showed that the current HbA1c criterion had a low specificity (69.4%) and may be inadequate alone. Consequently, we suggested that the HbA1c cut-off value should be revised for better sensitivity as well as specificity both to identify individuals in an early diabetic state. The early diabetic state, if correctly identified could prevent micro and macrovascular complications or delay progression. Based on our regression analysis, the equivalent HbA1c value in respect to FPG 126mg/dl was closer to 7.1%.

Using HbA1c as a test has an advantage that it measured average blood glucose over a 3-month period. Also, it didn't require patients to fasting of patients like in FPG and was performed via a single venepuncture unlike 2hPG, which entailled the patient to have food between blood draws. As the fasting status of the patient need not be verified and the cumbersome procedure of coordinating the ingestion of food and laboratory draws were not necessary, it provided convenience for patients testing for HbA1c and for health providers it simplified diabetes screening.

However, limitations to reflect chronic hyperglycaemia in HbA1c have been reported.[29] In high red blood cell turnover patients, due to the shortened life spans of red blood cells, HbA1c may be falsely lowered as the percentage of glycated haemoglobin was lowered regardless of the level of hyperglycaemia in blood.

Unreliable HbA1c was also reported in patients with hemoglobinopathy. The other contributory factor to the discordance between HbA1c and glucose levels in patient's serum was the differing levels of glycation.[30] The established or confirmed diagnosis of diabetes cannot be based on a single test but rather by repeated measurement of FPG, 2hPG or HbA1c.[31]

HbA1c had lower within-person variability (within-person coefficient of variation (CV): 3.6%; 95% CI: 3.2, 4.0) as compared to 2hPG (CV: 16.7%; 95% CI: 15.0, 18.3) and FPG (CV: 5.7%; 95% CI: 5.3, 6.1) [32]. Thus, HbA1c could be more reproducible than 2hPG and FGP.

Limitations

A clear limitation of the study was that the current study did not allow for any assessment of the clinical significance of the failure to detect a substantial proportion of patients having diabetes using the using FPG or 2hPG levels by the current HbA1c criterion, although it was clearly demonstrated.

CONCLUSION

HbA1c should be used cautiously and as a supplement to FPG and 2hPG to accurately define the prevalence and to avoid the underdiagnosis. Our data demonstrate that the HbA1c criterion is much less specific than FPG and 2hPG in diagnosing diabetes. HbA1c of 7.1% could be used as the cut-off value to be in agreement with FPG and 2hPG and to prevent delay in diagnosis, surveillance and ultimately the treatment. However, a longitudinal study is required before recommendations of using this cut-off value, to demonstrate its effects on long-term diabetic complications. Regardless, our results support that FPG and/or 2hPG should be used for early diagnosis of diabetes when the diagnosis by HbA1c is in doubt.

Recommendations

Further studies should focus on whether the complications such as neuropathy and nephropathy, increase when HbA1c reaches 7.1%. Also, they should investigate the temporal influences on the discordance between the HbA1c and FPG/2hPG criteria. Due to this discordance, patients with missed diagnosis using HbA1c may eventually be diagnosed with diabetes in the next few months or years using the same HbA1C criterion. So, it will be clinically significant to study this. Also, whether this delay will have any deleterious effect on the health of an individual should also be investigated.

ACKNOWLEDGEMENTS

The authors would like to thank the director Dr. Kirti M. Patel and the dean Dr. Yogendra Modi of GCS medical hospital college and research centre for providing with the permission to carry out this case report. Also, the authors would like to thank Dr. Rosy Lekharu Pradhan for her immense support in carrying out this project.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Khandhedia P, Sharma K, Pradhan R. Significance of diagnostic and monitoring criterion of HbA1c as compared with fasting and 2-hour plasma glucose concentration in GCS general hospital, Ahmedabad: a retrospective study. Int J Res Med Sci 2022;10:850-61.