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Original Article

Glycated Albumin's Clinical Effectiveness in the Diagnosis of Diabetes

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ABSTRACT

In places like Asia, the use of Glycated Albumin (GA) as a diabetes diagnostic marker has increased in recent years. Glucophage (GA) has been shown to be effective in the diagnosis of diabetes in asymptomatic people who have medical records and rising blood glucose levels that indicate a high risk of acquiring diabetes. **Objective:** To find out the impact of glycated albumin in the diagnosis of diabetes mellitus. **Methods:** This study included a total of 250 participants including one or even more diabetes risk factors or Fasting Plasma Glucose (FPG) varying from 5.6 molar ratio to 6.9 molar ratio but no symptoms of diabetes. The lab Taurus device was used to assess plasma GA using an enzymatic technique. **Results**: Among the patients, 20(6.9%) had *HbA1c* greater than 49 molar ratio. As per the outcomes, GA's diagnosed diabetic participants with a sensitivity of 73.6% (95% confidence interval: 44.4 – 92.4) and a specificity of 74.5% (95 % confidence interval: 44.4 – 92.4) at a cut-off of 15% (Area under the *ROC curve*: 0.79; 96%, CI: 0.79-0.99; *P≤ 0.01*), which corresponds to the better diagnostic performance. At different cut-offs for diabetes diagnosis, the specificity and sensitivity of GA are examined. The 14.2% cut-offs were linked with greater sensitivity (89.5%; 96%, CI: 59.2 – 89.5) and adequate specificity (63.6%; 95%, CI: 52.9 – 66.5), making it more appropriate for screening at-risk individuals. **Conclusions:** This research proves the clinical efficacy of GA for diabetes diagnosis participants at risk for the disease. Further investigation is required to evaluate the relative relevance of GA in relation to the other diabetes screening indicators.

INTRODUCTION

Fasting Plasma Glucose (FPG) is often used in medical practice for years to diagnose glucose homeostasis abnormalities. As reported by various worldwide guidelines, FPG is a simple and cost-effective screening to identify patients with diabetes as well as Impaired Fasting, which is believed to be the main risk factor for diabetes [1,2]. Second-tier diagnostic tests for hyperglycemia and concealed diabetes include oral glucose tolerance testing, yet their increasing popularity is restricted by increased prices, as well as reduced patient compliance and reliability. As a screening test for diabetes, HbA1c was added to the FPG and Glucose levels in 2009 [3,4]. Furthermore, there is a lack of coherence among the many criteria [1], diagnostic criteria for both prediabetes and diabetes have been connected to differing outcomes [5]. The inadequate agreement among multiple clinical guidelines, such as Fasting blood glucose, 2hPG, and HbA1c, can be described by the 3 indicators' varied approaches to glucose balance (fasting glucose, postprandial glucose, and the average glucose levels,

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respectively). The same diagnostic criteria, particularly FPG greater than 7 molar ratio or HbA1c greater than 48 molar ratio as well as 2hPG greater than 11.1 molar ratio, must be validated in asymptomatic patients on a subsequent occasion, which can delay the diagnosis of diabetes [6,7]. Quick diagnosis and appropriate glucose homeostasis treatment are required to lower the severity and duration of hyperglycemia exposure and improve cardiovascular risk in people who have diabetes [8]. Despite the greater costs, some believe that screening for diabetes using Fasting blood glucose plus a secondary measure like HbA1c is a more accurate way to detect the disease[9]. These biomarkers, such as GA, fructose amine, and 1,5-anhydroglucitol, have been suggested to strengthen the description of glucose abnormalities and to increase their efficiency [10]. In comparison to Fasting glucose and Glycosylated hemoglobin, Variable biomarkers of gluconeogenesis may be measured using GA [11,12]. GA ratio is two to three times higher than that of other circulatory proteins in hypoglycemic situations due to the longer duration and high plasma levels content [7,13]. Current data has also suggested its importance as a predictor of onset diabetes, vascular diseases, and cardiac consequences [14] as well as a predictor of glycemic variation [15,16]. Since its introduction as a screening test for blood donors and the general population in Asia, GA has shown to be a very useful tool for the early detection of diabetes [17]. The therapeutic efficacy of GA in the diagnosis of diabetes in persons who are regarded at risk of developing diabetes based on their medical history will be examined using medical history, physical examination, and Fasting Blood Glucose levels.

METHODS

From July 2018 to January 2019, 250 participants in a row at the laboratory of Lady Reading Hospital were enrolled. The inclusion criteria were as follows:

a) Diabetic risk 1 or even more, and FPG varying from 5.6 - 6.9 molar ratio at inclusion

b) No characteristic hyperglycemia signs (frequent urination, polydipsia, and loss of weight)

c) Age greater than 18 years

d) Peshawar ethnic

Obesity is a risk factor, a body mass index of 25 kg; a previous *HbA1c* ratio of 39 molars to 47 molar; Fasting Consumption of glucose Women's fasting tolerance, diabetes history, and pregnancy-related diabetes history. The patient has a history of cardiovascular disease, hypertension 130/80 mmHg, HDL- Cholesterol 0.9 molar ratio or higher, and PCOS. Anemia, blood disorders, blood transfusions, pregnancy, liver cirrhosis condition, malignancy condition, and any acutely critical situation and ethnicity not from Peshawar were all excluded. At the time of registration, samples of blood were taken, and comprehensive medical history and informed written permission were received. In accordance with local ethical requirements, the research proposal was accepted, and all participants signed a written permission form.

Laboratory procedure:

To ensure accurate results, blood samples for all tests, such as *HbA1c* and GA, were collected while subjects were fasting. FPG, *HbA1c*, and clinical laboratory values were evaluated immediately after the collection of samples at the recruiting location. The (CKD EPI) formula was used to determine EGFR [18]. HbA1C was evaluated at the laboratory of the Lady Reading Hospital using the Bio-Rad instrument and reagents, and at the other sites using the Menarini Diagnostic's apparatus and reagents. These procedures use ion technology. There is a significant level of relationship between the two tests. For each site, plasma K2-EDTA for GA measurement was added to the samples and kept at -80 degrees. All plasma GA data were measured on an I lab Taurus analyzer using an enzymatic approach. GA and total albumin may both be measured using this approach. The actual High-performance liquid chromatography (HPLC) result is converted from the GA value acquired using the enzyme technique [19]. The concentration of GA is expressed as a proportion of overall albumin. The assay's precision was assessed using control samples provided by the reagents' manufacturers. Within both CV percentages were 3.0% and 1.2% respectively, at a low concentration of 15.1%. Among and within run CV percentages were 2.5% and 0.9% respectively, at high concentration (32.1%). The Homa2 Calculator v2.0 to determine the Homa-IR value.The *Shapiro-Wilk, Mann-Whitney test, Spearman's correlation* statistic was used. The *Shapiro-Wilk test* was used to determine the uniformity of the ranges for each variable. For categorical data, a *Chi-squared test* was used to assess differences among groups. Both normally and nonnormally distributed data were tested using the *Mann-Whitney test*. *Spearman's correlation* was used to assess the association between *HbA1c* and the other parameters. A *Receiving Operation Curves (ROC)* data was analyzed on participants with diabetic whose *HbA1c* was less than 46 molar ratios to examine the therapeutic utility of GA. All tests were accepted with a statistical significance of $P \leq 0.05$. SPSS V 2.32 was used for all statistics.

RESULTS

This study included 250 participants belonging to Peshawar. The average age was 40 years (IQR: 30–50), and 98 (35%) of the participants were males. GA's values obtained were 14.0% (IQR:11.0–15.9) and were not

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distributed properly. Neither of the subjects had FPG levels greater than a 6-molar ratio, 155 had FPG levels between 4.8 and 5.9 mmol/L. GA was found to be strongly linked with HbA1c in the entire group (R=0.22; P= 0.01). HbA1c levels were also linked to age (R=0.42; p≤0.01), Body Mass Index (R=0.12; P≤0.03), FPG (R=0.46; p≤0.01), glomerular filtration rate (R=-0.52; P≤0.01), High density lipoprotein cholesterol (R=-0.11; p≤0.01), Triglycerides (R=0.29; p≤0.01), Insulin hormone (R=0.42; p≤0.03) and HOMA-IR (R=0.20; P≤0.01). Key demographic, chemical, and medical features of the individuals based on HbA1c values are listed in Table 1. In addition, 202 patients (70.9%) had HbA1c less than 40 molar ratio, 80 (29.6%) had HbA1c between 40 and 49 molar ratios, and 20, (6.9%) had HbA1c greater than 49 molar ratios. GA was significantly greater in patients with HbA1c greater than 49 molar ratios than in those with HbA1c 40–49 molar ratio and in those with HbA1c 40 molar ratio (16.2% [Interquartile range: 12.5– 21.4] vs 14.5% [Interquartile range: 11.9– 16.5] and against 14 % [Interquartile range: 13.4– 14.7]; p≤ 0.05 for both comparisons) as shown in Table 1.

Parameters / subjects		HbA1c		
		< 40 mmol /mol	40 to 49 mmol/mol	> 49 mmol/ mol
Sample number	250	202 (70.9%)	80 (29.6%)	20 (6.9%)
Age	42 (30-50)	34 (20 -40)	56 (46 -60)	65 (55-60)
Males	96 (36 %)	55 (22.9%)	39.4 (42.8 %)	15 (10.6)
Body mass index	22 (20-26)	24 (22-25)	25 (23-26)	26 (24- 28)
Glycated Albumin	16.2 (12.5– 21.4)	14.5 (11.9-16.5)	14 (13.4 -14.7)	14.5 (11.9 -21.4)
Fasting plasma glucose	5.6 (3.9- 7)	5.0 (4.4 -5.0)	7 (4.9-6.0)	5.9 (5.2 – 6.1)
HbA1c	38 (3.6- 40)	32 (4.2 -4.9)	41.6 (39- 43)	52 (49-64)
EGFR	98 (86- 118)	110 (93- 122)	87 (69-89)	82 (50- 92)
Cholesterol	4.0 (3.4 -4.9)	4.2 (3.9 -4)	4.6 (4.1 – 5.2)	3.9 (3.4 -4.2)
HDL Cholesterol	1.6 (1.2 -1.6)	1.2 (1.1-1.8)	1.5 (1.2-1.8)	1.3 (0.6 -1.7)
Triglycerides	0.6 (0.8 – 1.7)	0.6 (0.82 – 1.17)	1.22 (0.29 – 1.89)	1.6 (1.88 – 1.59)
Insulin	6.9 (4.3 – 13.8)	7.6 (4.8 – 12.7)	8.2 (4.9 – 15.7)	10.8 (6.9– 18.7)
HOMA=IR	1.35(0.66 – 1.82)	1.88 (0.99 – 1.79)	1.45 (0.55 – 1.76)	2.1 (1.9 – 2.25)

Table 1: Individuals' demographic, chemical, and medical features based on HbA1c results

A receiver operating characteristic curve analysis was used to examine the therapeutic efficacy of GA in the diabetes diagnosis. As per the outcomes, GA's diagnosed diabetic participants with a sensitivity of 73.6% (95% confidence interval: 44.4 – 92.4) and a specificity of 74.5 percent (95 % confidence interval: 44.4 – 92.4) at a cut-off of 15% (Area under the ROC curve: 0.79; 96%, CI: 0.79-0.99; P≤0.01), which corresponds to the better diagnostic performance figure 1.

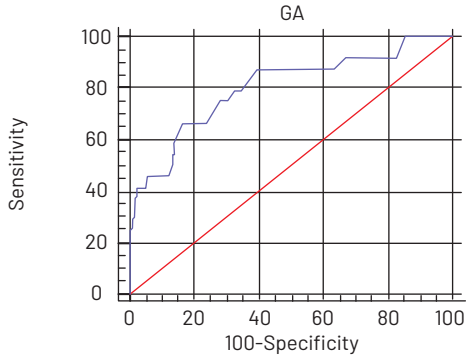

Figure 1: Diabetes diagnosis is based on the ROC curves of the GA (Area under curve: 0.90; 95% CI: 0.70-0.79; P≤ 0.01)

Table 2 shows the sensitivity and specificity of GA at different cut-off points for diabetes diagnosis. The 14.2% cut-offs were linked with greater sensitivity (89.5%; 95% Confidence Interval: 59.2 – 89.5) and adequate specificity (63.6%; 95% confidence interval: 52.9 – 66.5), making it more appropriate for screening at-risk individuals.

Values of cut off	Specificity	Sensitivity	Ratio of Positive	Ratio of Negative
14.2	63% (52.9 -66.5)	89.5 % (59.5 – 89.5)	1.0 (0.9 – 5.7)	0.39 (0.2 – 0.8)
14.5	72.2 % (47.7 – 89.7)	74.9 % (65.6 – 77.9)	2.22 (2 – 3.6)	0.18 (0.05 – 0.7)
14.9	60.3 % (36.9 – 99.0)	88.3 % (82.5 – 88.5)	3.9 (2.5– 6.9)	0.11 (0.6 – 0.13)
15.1	56.7 % (32.9 – 79.4)	85.6 % (84.1 – 92)	4.28 (2.3 – 6.7)	0.49 (0.2 – 0.55)

Table 2: Sensitivity and specificity measures, as well as the positive and negative ratios they generated

DISCUSSION

Glycated albumin (GA) is an intermediate glycemic control index that has become widely utilized in China. GA can be quantified using column chromatography methods, which need specialized knowledge and are restricted by high prices and a lack of efficiency. In the past few years, an enzyme test for GA detection has been developed, overcoming the challenges of chromatography approaches, and enabling large-scale- scale usage. Currently, the GA assessment is a conventional fully-automated technique for data processing analysis, ensuring better accuracy [20]. According to international recommendations, FPG, 2h-PG, and HbA1c can all be used to detect and diagnose diabetes [1]. It is well established that FPG levels can rise in a variety of circumstances that are not typically connected to diabetics, such as statin therapy, acute sickness, and anxiety [21,22]. HbA1c is more expensive and requires specialized equipment. Because of patients' low adherence to oral glucose tolerance test adherence of patients to oral glucose tolerance tests, low stability, pharmaceuticals, and anxiety, the 2hPG is not always acceptable in regular screening contexts. As a result, the invention of biomarkers that might minimize these restrictions and lead to a more precise diabetes diagnosis seems interesting. In terms of HbA1c GA's does not have fasting or other special client treatment, and it has

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less pre-analytical- analytical variation than glucose-based parameters [23]. Furthermore, as compared to HbA1c, it has several benefits. It can be assessed on the same analyzer as Fasting blood glucose and at a lesser rate than HbA1c such factors, GA, in conjunction with Fasting blood glucose, may be recommended with the first diagnostic for diabetes testing. The dual technique, such as Fasting blood glucose with Glycosylated hemoglobin, has been proposed to improve diabetes detection and considerably boost the prognosis of Fasting blood glucose alone during the occurrence of prospective diabetes [24]. Yet, because of the greater prices and low applicability of this approach, its use in substantial routine screening is reduced. In asymptomatic participants, our findings showed that GA's are an accurate indication for diabetes diagnosis. This study will be used to compare its therapeutic effectiveness to certain other diagnostic biomarkers such as Fasting blood glucose in the future GA's levels may be impacted by medical disorders associated with albumin transition that are independent of the diabetic state, such as cirrhosis of the liver, thyroid disorders, as well as End-Stage Kidney Diseases. As a result, more research is needed to determine the possible significance of GA's in such cases. When used on asymptomatic persons who were considered at risk based on their personal history and laboratory data, GAs performed very well at diagnosing diabetes in this study's Peshawar population (Area under the ROC curve: 0.79; 96%, CI: 0.79-0.99; p≤0.01). None of the variables that were strongly associated with HbA1c had an Area under the curve greater than GA in detecting diabetes. The value cut-offs of GAs showed greater sensitivity (89.5%; 96%, confidence interval: 59.2 – 89.5) and acceptable specificity (63.6%; 95%, confidence interval: 52.9 – 66.5), establishing its utility in the monitoring of diabetes in high-risk individuals particularly, the stability between specificity and sensitivity is attained at the cut-off of 14.5%, enabling the assay practically effective for diabetes detection in more widespread medical settings. Asymptomatic patients with one or more diabetes risk factors, but no detectable FPG, may benefit from using GA as a first screening measure, according to our findings. Frequently such patients are required to undergo additional tests to define the real metabolic status of the patient, such as OGTT or HbA1c, A biomarker not affected by the low compliance of the patients (such as for OGTT) or the need for dedicated instrument and higher costs (such as HbA1c) but with high sensitivity may help exclude the disease so reducing the number of patients that require additional tests, especially in a setting characterized by a low prevalence of the disease, Nevertheless, this clinical application of GA should be confirmed in larger studies specifically aimed at evaluating the clinical efficacy and cost-effectiveness of this approach in comparison to the use of traditional diagnostic criteria" [25]. African immigrants in the United States were studied to see if GAs could aid in the diagnosis of pre-diabetes. The findings were positive. It has been shown that there is a weak connection between GA and 2h-FP in individuals who have had oral glucose tolerance testing [26].This study's recommended value of cut-offs for diabetes detection is substantially lower than those proposed in earlier research [26-28]. Because of the varied research design, ethnicities, less illness frequency, and various diagnostic methods employed to classify participants (Fasting plasma, 2h-PG, HbA1c), the results are most likely related to the differences. As per the ROC curve, the GA cut-offs that significantly measured diabetes in the Okinawan Population Research, a large regional sample study done in Japan, was 15% with an Area under the curve of 0.87 [10]. Findings from a community-based research cohort of 1440 participants who underwent an Oral glucose tolerance test showed a sensitivity and specificity of 84% and 72% for GA for diabetes diagnosis, respectively, at a cut-off of 15% [26]. Although individuals in this research had equal FPG levels, they had slightly higher HbA1c and GA levels, which suggests a differential diagnosis for diabetes. In our research, only one HbA1c measurement of more than a 49-molar ratio was utilized as a factor for diagnosis of diabetes, which does not precisely acceptable with ADA recommendations. Nonetheless, short-term variable analysis has revealed that HbA1c is less volatile than Fasting blood glucose [29], A result of HbA1c of more than 49 molar ratio is a significant predictive factor in diabetes diagnosis, even in patients who did not match the criteria for a diagnosis based on Fasting blood glucose [29] validating the use of HbA1c for diabetes diagnosis on a single occasion. The optimal cut-off for diabetes diagnosis described in the present study is lower than the 99° percentile of the GA distribution in Peshawar blood donors 14.2%" [30]. Impaired Fasting Glucose was shown to be a less prevalent cause of the illness than previously thought (5.4%).

CONCLUSIONS

In the Peshawar population, GAs is useful in the diagnosis of diabetes. This supports its application in clinical practice for screening asymptomatic people deemed at risk for the condition (diabetes), enabling an early diagnosis and maybe reducing the number of subjects needing an oral glucose tolerance test (OGTT). The importance of GA in relation to other suggested diagnostic criteria for diabetes diagnosis must be explored further.

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