Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com/journal/sjams/home

OPEN ACCESS

Pathology

Diagnostic Utility of Glycated Hemoglobin (HbA1c) in Newly Diagnosed Type II Diabetes Mellitus Patients

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| **Received:** 10.01.2019 | **Accepted:** 20.01.2019 | **Published:** 30.01.2019
DOI: 10.36347/sjams.2019.v07i01.050

Abstract | **Original Research Article**

Nowadays due to sedentary lifestyle and increasing incidence of diabetes, standardized screening test for diagnosis of diabetes mellitus type II is necessary.DM type II is diagnosed by fasting blood sugar, post prandial blood sugar, random blood sugar, oral glucose tolerance test and glycated hemoglobin. In this study we are evaluating the role of HbA1c in diagnosis of type II DM patients by comparing it's results with RBS, FBS, PP2BS. Observational and prospective study.100 samples are taken since July 2016 to September 2017 who newly diagnosed as type II DM patients came at central clinical laboratory at c.u.shah medical college surendranagar. The results of HbA1c, RBS, FBS and PP2BS for 100 individuals were analysed. There were 100 newly diagnosed type II DM patients respectively.52 of them were females and 48 were males. The mean age of all patients is 43.5 ± 15.5 years. Diagnostic sensitivity of newly diagnosed DM type II by using HbA1c, RBS, FBS and PP2BS 82 %,71 %,51%,36 % respectively. As a Diagnostic tool for newly diagnosed DM II the HbA1c level performed better than RBS, FBS, PP2BS in our study. High diagnostic power of HbA1c may contribute to the decrease in the number of undiagnosed patients.
Keywords: Diabetes mellitus (DM), Glycated hemoglobin (HbA1c), FBS (Fasting blood sugar), PP2BS (Post prandial blood sugar), RBS (Random blood sugar).

INTRODUCTION

Glycated hemoglobin refers to hemoglobin to which glucose is attached nonenzymatically and irreversibly, its amount depends upon blood glucose level and lifespan of red blood cells [1].

Hemoglobin + Glucose ↔ Aldimine → Glycated hemoglobin

Plasma glucose readily moves across the red cell membranes and is being continuously combined with hemoglobin during the lifespan of the red cells (120 days). Therefore, some hemoglobin in red cells is present normally in glycated form. Amount of glycated hemoglobin in blood depends on blood glucose concentration and lifespan of red cells. If blood glucose concentration is high, more hemoglobin is glycated. Once formed, glycated hemoglobin is irreversible. Level of glycated hemoglobin is proportional to the average glucose level over preceding 120 days [2]. Glycated hemoglobin is expressed as a percentage of total hemoglobin. Normally, less than 5% of hemoglobin is glycated. Diagnosis of DM type 2 in early stage is good for person because late diagnosis can cause many complications [3, 4]. Diagnosis can be done by Fasting blood sugar ,Post Prandial Blood Sugar ,Random Blood Sugar ,Glucose Tolerance Test and HbA1C[5, 6]. Among them only HbA1c can't require patient preparation before testing.

MATERIALS AND METHODS

In this Observational and prospective study, 100 samples were taken from July 2016 to September 2017 who were newly diagnosed as type II DM patients and came to medicine department and central clinical laboratory. The results of HbA1c, RBS, FBS and PP2BS of 100 individuals were analysed. The diagnostic sensitivity of individual test was counted among 100 patients. This study is approved by ethical committee of C.U.Shah medical college.

Tests are performed with the following steps

- **FBS:** After 8 hrs fasting period, blood samples were taken by phlebotomy into floride test tubes

between 8:00 AM to 10:00 AM. Serum glucose level was measured by a enzymatic method.

- **PP2BS:** After 2 hrs of lunch period, blood samples were taken by phlebotomy into floride test tubes. Serum glucose level was measured by a enzymatic method.
- **RBS:** At any random time blood samples were taken by phlebotomy into floride test tubes. Serum glucose level was measured by a enzymatic method.
- **HbA1c:** After 8 hrs fast concurrently with FBS or 2 hrs of lunch period along with PP2Bs blood samples were taken by phlebotomy at any random time in EDTA test tubes. HbA1c result was calculated as a ratio to total hemoglobin by HPLC (A1C%).

RESULTS

In our study out of 100 cases 52 were female and 48 were male patients. The most commonly affected patients are between the age of 40 to 60 years. Individual test's Diagnostic sensitivity of newly diagnosed DM type II among 100 patients were.

HbA1c 82 %
RBS 71 %
FBS 51 %
PP2BS 36 %

Table-1: Male to female ratio of DM-II Patients

	Female	Male
No of cases	**52**	48

Among 100 patients 52 were female and 48 were male.

Table-2: Age wise distribution

AGE GROUP	
30-39	13
40-49	44
50-60	43
Total	100

Among 100 patients 44 patients were from age group 40-49.

Table-3: Diagnostic sensitivity by different tests of DM type II patients

Tests	Sensitivity in %
RBS	71
FBS	51
PP2BS	36
HbA1c	82

Among these the diagnostic sensitivity of HbA1c is 82% from 100 patients.

DISCUSSION

The incidence of diabetes is serious and growing public health problem, because of it peoples life expectancy reduced [7, 8]. Diabetes mellitus type II is a long term metabolic disorder that is characterized by high blood sugar, insulin resistance and relative lack of insulin [9]. On long standing microangiopathy complications occurs in DM type II like retinopathy, nephropathy and neuropathy [6, 10]. So due to increased incidence of DM type II and prevent complications of DM, early stage diagnosis is necessary. Diabetes mellitus is diagnosed by measuring blood glucose level. Measurement of blood glucose level is a simple test to assess carbohydrate metabolism in DM. Since glucose is rapidly metabolized in the body, blood glucose measurement is indicative of current state of carbohydrate metabolism.[1][11]DM type II is diagnosed by fasting blood sugar, post prandial blood sugar, random blood sugar, glucose tolerance test and glycated haemoglobin.[7][10]Among these HbA1c is highly standardized test for newly diagnosis of type II DM patients, because other tests result get affected negative or positive due to diet. Whenever HbA1c give long term glucose level of about 120 days which give proper result. One can do HBA1c at any time, no patient preparation is needed. For diagnostic criteria of diabetes mellitus type II Values are as below [5]

- Symptoms of diabetes plus random blood glucose concentration: ≥200 mg/dl or
- Fasting plasma glucose:≥126 mg/dl or
- 2-h plasma glucose: ≥200 mg/dl or
- Hemoglobin A1c : ≥6.5%

Pre-diabetic Values

- FBS: 100-125 mg/dl
- 2-h plasma glucose : 140-199 mg/dl
- HbA1C: 5.7-6.4 %
- For HbA1c diagnostic criteria:[5]
- <5.6 %- normal glucose tolerance
- 5.7-6.4-Impaired glucose tolerance

≥6.5 Diabetes Mellitus

- Therapeutic goals for glycemic control
- Goal of therapy: <7.0 % HbA1c
- Action Suggested:>8.0% HbA1c

An international committe of diabetes experts has recommended that HbA1c is now routinely used to monitor the course of the disease and should become the new gold standard test for diagnosis of DM type II patients [9, 12]. In our study we tested 100 patients by FBS, PP2BS, RBS and HbA1c. Among them Diagnostic sensitivity of newly diagnosed DM type II by using HbA1c, RBS,FBS and PP2BS 82 %,71 %,51%,36 % respectively.

So among this most sensitive result we can get by using HBA1c.

We compare it with other study of Naser Alqahtani about use of glycated haemoglobin in the diagnosis of diabetes mellitus and pre-diabetes and role of fasting plasma glucose, oral glucose tolerance test published in 2013.In their study the diagnostic sensitivity of HbA1c is 69.6% and 43.1% for FBS.

CONCLUSION

As a Diagnostic tool for newly diagnosed DM type II, the HbA1c level performed better than FBS, PP2BS, RBS. So HbA1c can be utilized as a diagnostic marker not just used in monitoring the treatment.

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