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A Comparative study of Glycosylated Haemoglobin (HbA1c) with fasting blood glucose levels in the Diagnosis of type 2 Diabetes Mellitus patients.

Rakesh Dhir[1], B Shaheed Abdul Ansar[1*], Naga Babu Pyadala[2], Khaji Sana Farheen[3]

1. *Assistant Professor, Department of General Medicine, MNR Medical College and Hospital, Sangareddy, Telangana, India-502294.*
2. *Professor, Department of Biochemistry, MNR Medical College and Hospital, sangareddy, Telangana, India-502294.*
3. *Post Graduate, Department of Radio-diagnosis, MNR Medical College and Hospital, Sangareddy, Telangana, India-502294.*

**Corresponding Author: Dr. B Shaheed Abdul Ansar*
Assistant Professor, Department of General Medicine, MNR Medical College & Hospital, Sangareddy, Telangana,

Abstract:
Introduction: *Diabetes mellitus (DM) is a most popular and complex metabolic disorder characterized by persistently elevated levels of blood glucose with disturbance of carbohydrates, proteins, and fats metabolism as a result of a defect in an insulin production or its action or both.* ***Aim:*** *The aim of the present study was taken to compare the efficiency of fasting blood glucose and HbA1c, in the diagnosis of type 2 DM.* ***Material & methods:*** *This cross sectional study was conducted at MNR Medical College Hospital from August 2021 to January 2022. The data collection which includes FBS and HbA1C values of around 423 type 2 diabetic patients was done. This includes 246 males and 177 females. The study population was divided into three groups based on the HbA1c values i.e. Group 1(HbA1c 6.5% – 7.0% (Good control)), Group 2 (HbA1c 7%-9% fairly controlled), Group 3 (HbA1c >9% (Poorly controlled). Blood glucose was estimated by using GOD-POD method and HbA1c estimated by using ERBA glycohemoglobin kit (Ion-exchange resin method).* ***Results:*** *The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 1 is 171.2 ± 10.67 and 6.77 ± 0.021 respectively. The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 2 study subjects were 210.02 ± 22.72 and 8.08 ± 0.686 respectively. The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 3 study subjects were 276.63 ± 44.79 and 10.42 ± 0.916 respectively. It was evident that fasting blood glucose and HbA1c levels are increased in group 2 and group 3 compared to group 1. One sample t test showed that there was significant correlation between fasting blood glucose with HbA1c in all the three groups ($p<0.0001$).* ***Conclusion:*** *Our study shows that HbA1c can be used effectively along with blood glucose for the diagnosis of type 2 DM and it can be used as a screening test to predicting the complications of type 2 DM.*

Keywords: *Type-2 diabetes mellitus, Fasting blood glucose, HbA1C, diagnosis of diabetes. Glycemic control.*

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I. Introduction:

Diabetes mellitus (DM) is a most popular and complex metabolic disorder characterized by persistently elevated levels of blood glucose with disturbance of carbohydrates, proteins, and fats metabolism as a result of a defect in an insulin production or its action or both [1-3]. DM causes long term complications that include dysfunction and damage to various organs like kidneys, eyes, heart, and blood vessels. According to Abdulfatai B et al., by 2030 there will be 553 million people effected with DM, among that 439 million people will be effected with type 2 DM [2]. Globally, the prevalence of DM is increasing day by day. Among DM the prevalence of type 2 DM is increasing significantly in south asian population, especially in developing country like India. The prevalence is increasing day by day due to several factors like lack of physical activity, high level of insulin resistance and increased obesity [4-7]. If type 2 DM goes untreated, leads to hyperglycaemia that can affect organs and cells in the body. The major complication of type 2 DM includes retinopathy,

nephropathy, neuropathy, cardiovascular disease and stroke. Therefore, regular monitoring is recommended to prevent the development of complications and thereby improving the quality of life. For decades, the diagnosis of DM was based on fasting blood glucose (FBS) or oral glucose tolerance test (OGTT), but some limitations are there to utilise these methods. So in 2009 American Diabetes Association (ADA) and International Diabetes Federation recommended the use of glycated haemoglobin (HbA1c) test to diagnose diabetes with a threshold of ≥ 6.5% [8-13]. HbA1c will reflect the average plasma glucose level over a previous 8 to 12 weeks. Hence, the present study was taken to compare the efficiency of fasting blood glucose and HbA1c, in the diagnosis of type 2 DM.

II. Methods And Materials:

This cross sectional study was conducted at MNR Medical College Hospital from August 2021 to January 2022. The data collection which includes FBS and HbA1C values of around 423 type 2 diabetic patients was done. This includes 246 males and 177 females. The study population was divided into three groups based on the HbA1c values i.e. Group 1(HbA1c 6.5% – 7.0% (Good control)), Group 2 (HbA1c 7%-9% fairly controlled), Group 3 (HbA1c >9% (Poorly controlled).

Collection of blood sample:

Blood samples were collected, after 12 hours fast from the above study subjects. 5ml of blood from the cubital vein collected in tubes containing sodium fluoride, EDTA, and bottle, after explaining the procedure to the study subjects. Serum was separated from the blood samples by a centrifuged machine at 3000 rpm for 10 minutes in the biochemistry department. Following estimations are carried out on the serum samples by standard kit methods, and analyses performed on ERBAsemi auto-analyzer.

Parameters measured: In the present study following parameters were measured:

- Fasting Blood Glucose
- Glycated haemoglobin (HbA1c)

Blood glucose was estimated by using GOD-POD method and HbA1c estimated by using ERBA glycohemoglobin kit (Ion-exchange resin method) [13].

Reference range: The standard reference ranges according to the kits are as follows. Fasting blood glucose (normal range 70-126 mg/dl), and HbA1c (normal range 4.2-5.7%, pre diabetes 5.7% to 6.4%, diabetes > 6.5) [14].

Statistical Analysis: The collected data were analyzed by SPSS software version 16.0.

III. Results:

In the present study, total 423 subjects divided into three groups, 79 group 1 study subjects (good control), 123 group 2 study subjects (fairly controlled) and 221 group 3 study subjects (Poorly controlled) with the age range of 30 – 80 years (Table 1). Out of 79 group 1 study subjects, 52 were males and 27 females , out of 123 group 2 study subjects, 77 were males and 46 females, out of 221 group 3 study subjects, 117 were males and 104 females as shown in the [Figure 1-3].

Table 1: Gender and age wise distribution of study subjects (n=423)

Age (years)	Group 1 (n=79)		Group 2 (n=123)		Group 3 (n=221)	
	Males (n=52)	Females (n=27)	Males (n=77)	Females (n=46)	Males (n=117)	Females (n=104)
30-40	07	01	03	05	13	09
41-50	09	03	09	11	21	34
51-60	12	09	23	14	32	26
61-70	20	14	39	09	38	31
71-80	04	00	03	07	13	04
Total	79		123		221	
	423					

Figure 1 : Gender wise distribution of Group 1 (good control) study subjects

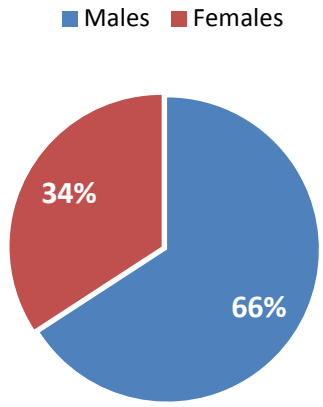

Figure 2 : Gender wise distribution of Group 2 (fairly controlled) study subjects

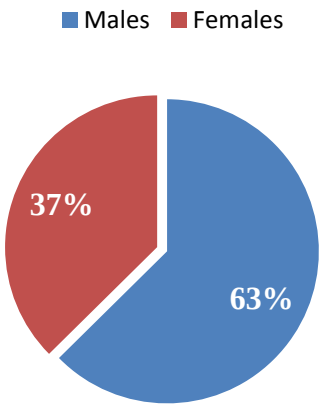

Figure 3 : Gender wise distribution of Group 3 (poor control) study subjects

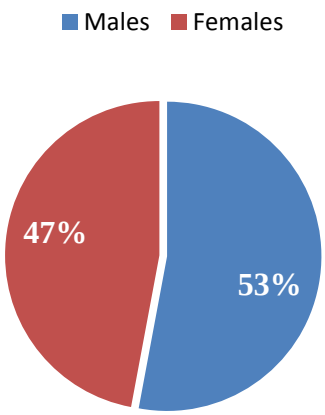

Table 2: Mean fasting blood glucose and Mean HbA1c levels in the study group							
Parameters	**Group1** (Good control)		**Group 2** (fairly controlled)		**Group 3** (Poor control)		
	Mean ± SD	**SEM**	**Mean ± SD**	**SEM**	**Mean ± SEM**	**SEM**	**p value**
Mean Fasting Blood Glucose	171.2 ± 10.67	1.22	210.02 ± 22.72	2.05	276.63 ± 44.79	3.01	<0.0001*
Mean HbA1c	6.77 ± 0.021	0.021	8.08 ± 0.686	0.062	10.42 ± 0.916	0.063	<0.0001*

Standard error of the mean (SEM) & * Extremely Statistically Significant.

The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 1 is 171.2 ± 10.67 and 6.77 ± 0.021 respectively. The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 2 study subjects were 210.02 ± 22.72 and 8.08 ± 0.686 respectively. The mean and standard deviation (Mean ± SD) values of fasting blood glucose and HbA1c among group 3 study subjects were 276.63 ± 44.79 and 10.42 ± 0.916 respectively [Table 2]. it was evident that fasting blood glucose and HbA1c levels are increased in group 2 and group 3 compared to group 1 [Table 2]. One sample t test showed that there was significant correlation between fasting blood glucose with HbA1c in all the three groups ($p<0.0001$) [Table 2].

IV. Discussion:

DM is a chronic illness that requires patient education, support and medical care to prevent acute complications and to reduce the long term complications. Several methods are used to assess the blood glucose levels among DM patients. This includes assessment of blood glucose and glycated haemoglobin (HbA1c). HbA1c is formed through the non-enzymatic reaction and its levels are increased when high concentrations of blood glucose are seen in the patients. The high concentrations of HbA1c levels will predict the complications of diabetes. In the present study, there is a correlation between HbA1c and fasting blood glucose. Similar studies were reported by Weerarathne TP et al., [15], Swetha N K,[16], Catherine et al.,[17], Wenyu Wang et al.,[18], Woo-Jun Yun et al., [19], Kharroubi AT et al., [20] .

V. Conclusion:

Our study shows that HbA1c can be used effectively along with blood glucose for the diagnosis of type 2 DM and it can be used as a screening test for predicting the complications of type 2 DM.

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