

## LEVEL OF HbA1c AND FACTORS ASSOCIATED IN DIABETES MELLITUS

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**Abstract**

**Background:** The number of people with diabetes and pre-diabetes is exponentially increasing worldwide due to population growth, aging, urbanization, unhealthy eating habits and increasing prevalence of obesity. The number of people with diabetes in India is increasing. HbA1c reflects the control of blood glucose levels and various factors affect the levels. Hence there is an need to estimate the level of HbA1c among the patients with Type 1 and Type 2 Diabetes Mellitus and to determine the factors associated with the abnormal HbA1c levels. **Materials and Methods:** This cross-sectional study was conducted among 103 diabetes mellitus patients in Government Villupuram Medical College Hospital among the diabetes mellitus patients attending the NCD clinic. Data were collected using semi structured questionnaire. Blood samples were collected to estimate the HbA1c levels. Data were entered in MS Excel and analysed using SPSS software. Appropriate descriptive and inferential statistics were done, considering p value of <0.05 as statistically significant. **Result:** About 36 (35%) were having type 1 diabetes and 67 (65%) were having type 2 diabetes mellitus. Most of the participants belong to age group of 56 to 65 years (35%). About 87.4% were taking metformin alone and others taking metformin and glimepride. About 75.7% had checked their blood glucose levels. About 81.6% had received their diet counselling. About 83.5% were following the diet. About 99% were receiving the diabetes treatment from government institutions. The median HbA1c level is 7.9% with range of 5.2% to 16.2%. Those with diabetic family member have better HbA1c than those who doesn't (p 0.04). Those having weight loss has high HbA1c levels than those who doesn't have weight loss (p 0.005). **Conclusion:** The study showed that the median HbA1c level was 7.9% with range of 5.2% to 16.2%. Among the factors, weight loss and those without family history of diabetes were found to statistically high HbA1c levels. Strategies have to be framed to focus on maintaining the HbA1c levels by adherence to medications and diabetic treatment advice.

**INTRODUCTION**

Diabetes is a common endocrine disease that is affected by abnormally high levels of sugar in the blood. The sugar level in the blood is controlled by a hormone called insulin which is secreted by the pancreas and endocrine gland. If the production of insulin is low in the body then it causes diabetes. It is the leading cause of morbidity and mortality worldwide. There are three types of diabetes: Type 1 Diabetes: Pancreas fails to secrete enough insulin due to the destruction of  $\beta$  cells which secretes insulin. It is also called juvenile diabetes and insulin-dependent diabetes mellitus. Type 2 Diabetes: It is also called

non-insulin-dependent diabetes mellitus. In which the secretion of insulin is less, and cells fail to respond to insulin. Gestational Diabetes: It occurs in pregnancy due to high sugar levels in the blood. Symptoms of diabetes include excessive urination, increased thirst, and hunger, weight loss, slow wound healing, skin problems, and numbness in the feet. It may cause many severe health complications if not treated on time including cardiovascular disease, stroke, severe kidney diseases, eye damage, and diabetic ketoacidosis.<sup>[1]</sup>

The number of people with diabetes and pre-diabetes is exponentially increasing worldwide due to population growth, aging, urbanization, unhealthy

eating habits, increasing prevalence of obesity, and physical inactivity.<sup>[2]</sup> Diabetes mellitus is a leading cause of morbidity and mortality worldwide, with an estimated 346 million adults being affected in the year 2011.<sup>[3]</sup> Approximately 9% of the population worldwide is affected by diabetes.<sup>[4]</sup> The prevalence of diabetes has risen from 108 million to 422 million from 1980 to 2014.<sup>[5]</sup> The prevalence is expected to double between the years 2005–2030, with the greatest increases expected in low- and middle-income developing countries of the African, Asian, and South American regions. At present, 80% of the world's population with diabetes live in low- and middle-income countries.<sup>[6,7]</sup>

The number of people with diabetes in India increased from 26 million in 1990 to 65 million in 2016. The prevalence of diabetes in adults aged 20 years or older in India increased from 5.5% in 1990 to 7.7% in 2016. The prevalence in 2016 was highest in Tamil Nadu and Kerala (high extract, transform, load (ETL)) and Delhi (higher-middle ETL), followed by Punjab and Goa (high ETL) and Karnataka (higher-middle ETL). The age-standardized DALY rate for diabetes increased in India by 39.6% from 1990 to 2016, which was the highest increase among major non-communicable diseases. The age-standardized diabetes prevalence.<sup>[8]</sup>

The prevalence of diabetes in India has remained at 11.8% in the last four years, according to the National Diabetes and Diabetic Retinopathy Survey report released by the Health and Family Welfare Ministry. The survey conducted during 2015–2019 by Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Sciences, New Delhi also showed that the prevalence of known diabetes cases was 8.0% and new diabetes cases were 3.8%. "Males showed a similar prevalence of diabetes (12%) as females (11.7%). Known diabetics comprised 67.3% of participants, while 32.7% were new diabetics. The highest prevalence of diabetes was observed in the 70–79 years age group at 13.2%. Nearly 40% of known diabetes were diagnosed 1–4 years back while 5.3% of known diabetes cases reported diagnosis within the past year," the report said.<sup>[9]</sup>

HbA1c known as glycated hemoglobin was used to measure one's level of glucose control. This level indicates the average blood glucose level of the past 90 days, indicating the lifespan of RBCs. Level of 6.5% was recommended as the cutoff point for diagnosing diabetes mellitus. Elevated levels of HbA1c leads to various diabetic complications.<sup>[10–12]</sup> HbA1c is affected by various factors like patient characteristics, risk factors and illness among patients, adherence to diabetes management and few others. Hence this study aimed to assess the level of HbA1c and the factors associated with HbA1c level among the diabetes mellitus patients.

### Objectives

1. To estimate the level of HbA1c among the patients with Type 1 and Type 2 Diabetes Mellitus.

2. To determine the factors associated with the abnormal HbA1c levels.

## MATERIALS AND METHODS

This cross-sectional study was conducted among 103 diabetes mellitus patients in Government Villupuram Medical College Hospital among the diabetes mellitus patients attending the NCD clinic. Blood samples of 36 adult patients with type 1 diabetes mellitus and 67 adult patients with type 2 Diabetes mellitus age group of 30 to 80 yrs were selected from NCD Clinic, Government Villupuram Medical College, and Hospital setting for the study respectively. The HbA1c levels had been assessed by laboratory confirmation separately for type 1 and type 2 diabetes patients. Each patient was interviewed and confirmed eligibility, basic demographic status, and clinical symptoms, including a rapid assessment of patient eligibility for blood collection, smoking status, alcohol consumption status, characteristics, food habits, and treatment history information was collected on four pages of standardized proforma during covid19s second wave on April to June 2021, which was accomplished even though highly challenging. Pregnant women, HIV patients, renal disease patients, and pulmonary disease patients were not included in this study. Institutional Human Ethics committee approval was obtained. Patients were informed about the study and consent was obtained. Confidentiality were maintained.

A standardized procedure was followed to collect blood samples from the selected patients by qualified technicians, at Villupuram Government Medical College. 6ml blood was collected in the 6-mL Plain, royal blue-top vacutainer plastic trace element blood collection tube from each diabetic patient in the Department of Non-communicable Diseases, medical college hospital, where they come for routine checkups and treatment.

Ion-exchange high-performance liquid chromatography (HPLC) was done to assess the HbA1c levels. The VARIANT II TURBO Hemoglobin Testing System combines Bio-Rad's HPLC precision and variant detection with fast throughput to provide a comprehensive solution for HbA1c testing. VARIANT technology provides a comprehensive solution for HbA1c testing. Built for exceptional performance, the state-of-the-art, fully automated VARIANT II Hemoglobin Testing System delivers quality results at high- test volumes. The VARIANT II Hemoglobin Testing System offers complete automation, with positive sample tracking and powerful data management. Save time and minimize errors with whole blood primary tube sampling — no costly manual preparation required. Streamline workflow through continuous or batch sampling. Results and chromatograms are captured and archived by Bio-Rad's Clinical Data Management (CDM) software. CDM provides remote support and interfaces with laboratory

information systems (LIS) for optimal data management. Advanced diagnostics, user alerts, and prompts reduce costs and training time, while the QC Module tracks quality control. HbA1c results followed international standard ranges given in percentages. Typical results are below.

1. Normal: HbA1c below 5.7%
2. Prediabetes: HbA1c between 5.7% and 6.4%
3. Diabetes: HbA1c of 6.5% or higher

Data were collected on the 4 pages of the pre-designed proforma and entered into Excel after creating tables and data dictionaries. The data entry was independently verified by two data entry operators for its accuracy. The patient's income, weight, and height were missing the maximum due to the patient's refusal. The data set was imported to SPSS statistical software and analyzed following data-driven methodology.

Data were cleaned and mined by using exploratory preliminary data analysis box-plot, the measure of central tendency, and the measure of dispersion to know the data validation, missing information, and an outlier. Data were analyzed by the non-parametric method Mann-Whitney U test for differences in two groups' medians and The Kruskal-Wallis test was used for comparing more than two groups because data were in non-normal distribution for HbA1c of patient's characteristic comparisons. The probability value was ( $<0.05$ ) considered a 95% level of significance.

## RESULTS

The study was conducted among 103 diabetes mellitus patients, among whom 36 (35%) were having type 1 diabetes and 67 (65%) were having type 2 diabetes mellitus. The results are explained below.

[Table 1] depicts the sociodemographic characteristics of the participants. Most of the participants belong to age group of 56 to 65 years (35%), followed by 46 to 55 years (26.2%) and then

others. The median (range) age of the participants was 56 years (30-80). About 51.5% were females and 48.5% were males. About 90.3% were Hindu by religion, 96.1% were married and 68.9% were employed.

[Table 2] depicts the lifestyle factors among the participants. About 10.7% and 1.9% were past and current smokers respectively. About 9.7% each were past alcoholic and current alcoholics. About 90.3% takes mixed diet and 85.4% takes vegetables regularly. About 73.8% were involved in exercise regularly.

[Table 3] depicts the illness among the participants. About 68% had reported hypertension and 62.1% were taking hypertension medications. Nearly 28.2% of the participants had diabetic family members. About 42.7% reported eye problems, 17.5% reported heart problems, 17.5% reported nerve problems, 11.7% reported tooth problems, 24.3% reported foot problems, 14.6% reported skin problems and 2.9% reported kidney problems. About 54.4% reported extreme hunger, 62.1% reported having thirsty feel frequently, 53.4% were urinating frequently. About 61.2% had weight loss, 61.2% had reported fatigue and 19.4% reported slow healing sores. About 39.8% were anemic and 68% reported extreme tiredness.

[Table 4] depicts the diabetes management details among the participants. About 87.4% were taking metformin alone and others taking metformin and glimepride. About 75.7% had checked their blood glucose levels. About 81.6% had received their diet counselling. About 83.5% were following the diet. About 99% were receiving the diabetes treatment from government institutions. The median HbA1c level is 7.9% with range of 5.2% to 16.2%.

[Table 5] depicts the association between HbA1c levels and various factors. Those with diabetic family member have better HbA1c than those who doesn't ( $p 0.04$ ). Those having weight loss has high HbA1c levels than those who doesn't have weight loss ( $p 0.005$ ).

**Table 1: Sociodemographic details (N=103).**

S. No	Variable	Category	n	%
1	Age in years	Median (Range)	56	30-80
2	Age group	30 to 45 years	23	22.3%
		46 to 55 years	27	26.2%
		56 to 65 years	36	35%
		66 to 80 years	17	16.5%
2	Gender	Male	50	48.5%
		Female	53	51.5%
3	Religion	Hindu	93	90.3%
		Christian	7	6.8%
		Muslim	3	2.9%
4	Marital status	Married	99	96.1%
		Widowed	4	3.4%
5	Occupation	Employed	71	68.9%
		Not gainfully employed	32	31.1%

**Table 2: Lifestyle factors (N=103)**

S. No	Variable	Category	n	%
1	Smoking	Past smoker	11	10.7%
		Current smoker	2	1.9%
		Non-smoker	90	87.4%

2	Alcohol status	Past alcoholic	10	9.7%
		Current alcoholic	10	9.7%
		Non-alcoholic	83	80.6%
3	Diet	Mixed diet	93	90.3%
		Vegetarian	10	9.7%
4	Eat vegetables regularly	Yes	88	85.4%
		No	13	12.6%
		Not known	2	1.9%
5	Exercise regularly	Yes	76	73.8%
		No	24	23.3%
		Not known	3	2.9%

**Table 3: Illness (N=103)**

S. No	Variable	Category	n	%
1	Having Hypertension	Yes	70	68%
		No	23	22.3%
		Not known	10	9.7%
2	Having medicine for hypertension	Yes	64	62.1%
		No	26	25.3%
		Not known	13	12.6%
3	Having diabetic family members	Yes	29	28.2%
		No	49	47.6%
		Not known	25	24.3%
4	Have eye problems	Yes	44	42.7%
		No	50	48.5%
		Not known	9	8.7%
5	Have heart problems	Yes	18	17.5%
		No	76	73.8%
		Not known	9	8.7%
6	Have nerve problems	Yes	18	17.5%
		No	72	69.9%
		Not known	13	12.6%
7	Have tooth problems	Yes	12	11.7%
		No	78	75.7%
		Not known	13	12.6%
8	Have foot problems	Yes	25	24.3%
		No	65	63.1%
		Not known	13	12.6%
9	Have skin problems	Yes	15	14.6%
		No	74	71.8%
		Not known	14	13.6%
10	Have kidney problems	Yes	3	2.9%
		No	77	74.8%
		Not known	23	22.3%
11	Have extreme hunger	Yes	56	54.4%
		No	47	45.6%
12	Have frequent thirst	Yes	64	62.1%
		No	39	37.9%
13	Feel extreme tiredness	Yes	70	68%
		No	32	31.1%
		Not known	1	1%
14	Frequently urinating	Yes	55	53.4%
		No	47	45.6%
		Not known	1	1%
15	Have weight loss	Yes	63	61.2%
		No	37	35.9%
		Not known	3	2.9%
16	Have fatigue	Yes	63	61.2%
		No	37	35.9%
		Not known	3	2.9%
17	Have slow healing sores	Yes	20	19.4%
		No	79	76.7%
		Not known	4	3.9%
18	Anemia	Normal	49	47.6%
		Anemic	41	39.8%
		Non known	13	12.6%

**Table 4: Diabetes management details (N=103)**

S. No	Variable	Category	n	%
1	Diabetes treatment	Metformin	90	87.4%
		Metformin and Glimepride	13	12.6%
2	Checked your blood sugar	Yes	78	75.7%

		No	14	13.6%
		Not known	11	10.7%
3	Ever received diet counselling	Yes	84	81.6%
		No	15	14.6%
		Not known	4	3.9%
4	Follow that diet	Yes	86	83.5%
		No	2	1.9%
		Not known	15	14.6%
5	Institution for diabetes treatment	Government	102	99%
		Private	1	1%
6	HbA1c level	Median (range)	7.9	5.2 - 16.2

**Table 5: Association between HbA1c levels and various factors (N=103)**

S. No	Variable	Category	n	Median	Min-Max	p value
1	Age group	30 to 45 years	23	9.5	5.2-16.2	0.214
		46 to 55 years	27	8.8	5.9-14.8	
		56 to 65 years	36	7.7	5.5-12.3	
		66 to 80 years	17	6.9	5.7-11.9	
2	Gender	Male	50	7.7	5.5-16.2	0.513
		Female	53	7.9	5.2-14.8	
3	Smoking	Past/ Current smoker	13	7.4	5.7-12	0.371
		Non-smoker	90	8.1	5.2-16.2	
4	Alcohol status	Past/ Current alcoholic	20	7.7	5.6-12.4	0.887
		Non-alcoholic	83	7.9	5.2-16.2	
5	Diet	Mixed diet	93	7.8	5.2-16.2	0.659
		Vegetarian	10	8.1	5.2-16.2	
6	Eat vegetables regularly	Yes	88	8.3	5.2-16.2	0.347
		No/ Not known	15	7	5.2-13.3	
7	Exercise regularly	Yes	76	8.5	5.3-16.2	0.119
		No/ Not known	27	7.2	5.6-12.5	
8	Having Hypertension	Yes	70	7.5	5.2-16.2	0.095
		No/ Not known	33	9.5	5.8-14.8	
9	Having medicine for hypertension	Yes	64	7.5	5.2-16.2	0.148
		No/ Not known	39	9.1	5.5-14.8	
10	Having diabetic family members	Yes	29	7.1	5.5-16.2	0.040*
		No/ Not known	74	8.5	5.2-14.8	
11	Have eye problems	Yes	44	7.8	5.2-13.7	0.614
		No/ Not known	59	7.9	5.2-16.2	
12	Have heart problems	Yes	18	7.2	5.7-12.3	0.168
		No/ Not known	85	8.5	5.2-16.2	
13	Have nerve problems	Yes	18	7.2	5.5-12.3	0.168
		No/ Not known	85	8.5	5.2-16.2	
14	Have tooth problems	Yes	12	9.8	5.9-12.5	0.402
		No/ Not known	91	7.8	5.2-16.2	
15	Have foot problems	Yes	25	7.9	5.5-13.7	0.558
		No/ Not known	78	7.8	5.2-16.2	
16	Have skin problems	Yes	15	7	5.2-16.2	0.292
		No/ Not known	88	8.1	5.2-14.8	
17	Have kidney problems	Yes	3	6.3	5.5-8.2	0.133
		No/ Not known	100	7.9	5.2-16.2	
18	Have extreme hunger	Yes	56	7.7	5.2-13.7	0.763
		No/ Not known	47	8.2	5.2-16.2	
19	Have frequent thirst	Yes	64	8.5	5.2-14.8	0.093
		No/ Not known	39	7.5	5.2-16.2	
20	Feel extreme tiredness	Yes	70	7.5	5.2-13.7	0.076
		No/ Not known	33	9.4	5.7-16.2	
21	Frequently urinating	Yes	55	8.2	5.2-13.7	0.971
		No/ Not known	48	7.8	5.2-16.2	
22	Have weight loss	Yes	63	8.5	5.5-16.2	0.005*
		No/ Not known	40	7	5.2-12.5	
23	Have fatigue	Yes	63	7.6	5.2-16.2	0.647
		No/ Not known	40	8.2	5.2-14.8	
24	Have slow healing sores	Yes	20	8.1	5.6-16.2	0.381
		No/ Not known	83	7.9	5.2-14.8	
25	Anemia	Normal	49	8.5	(5.2-16.2)	0.251
		Anemic	40	7.5	(5.2-14.8)	
		Severely anemic	1	5.6	(5.6-5.6)	
26	Diabetes treatment	Metformin	90	7.9	5.2-16.2	0.873
		Metformin and Glimepride	13	7.8	6-12.4	
27	Checked your blood sugar	Yes	78	8.3	5.2-16.2	0.168
		No/ Not known	25	7.5	5.5-12.5	

28	Ever received diet counselling	Yes	84	8.1	5.2-16.2	0.211
		No/ Not known	19	7.5	5.2-13.3	
29	Follow that diet	Yes	86	8.1	5.2-16.2	0.444
		No/ Not known	17	7.1	5.7-12.5	
30	Institution for diabetes treatment	Government	102	7.9	5.2-16.2	0.089
		Private	1	5.2	5.2-5.2	
31	Diabetes type	Type 1	36	8.9	5.6-16.2	0.054
		Type 2	67	7.5	5.2-14.8	

\*p <0.05 – Statistically significant

## DISCUSSION

The study was conducted among 103 diabetes mellitus patients, among whom 36 (35%) were having type 1 diabetes and 67 (65%) were having type 2 diabetes mellitus. Most of the participants belong to age group of 56 to 65 years (35%), followed by 46 to 55 years (26.2%) and then others. The median (range) age of the participants was 56 years (30-80). About 51.5% were females and 48.5% were males. About 90.3% were Hindu by religion, 96.1% were married and 68.9% were employed.

About 10.7% and 1.9% were past and current smokers respectively. About 9.7% each were past alcoholic and current alcoholics. About 90.3% takes mixed diet and 85.4% takes vegetables regularly. About 73.8% were involved in exercise regularly. About 68% had reported hypertension and 62.1% were taking hypertension medications. Nearly 28.2% of the participants had diabetic family members. About 42.7% reported eye problems, 17.5% reported heart problems, 17.5% reported nerve problems, 11.7% reported tooth problems, 24.3% reported foot problems, 14.6% reported skin problems and 2.9% reported kidney problems. About 54.4% reported extreme hunger, 62.1% reported having thirsty feel frequently, 53.4% were urinating frequently. About 61.2% had weight loss, 61.2% had reported fatigue and 19.4% reported slow healing sores. About 39.8% were anemic and 68% reported extreme tiredness.

About 87.4% were taking metformin alone and others taking metformin and glimepride. About 75.7% had checked their blood glucose levels. About 81.6% had received their diet counselling. About 83.5% were following the diet. About 99% were receiving the diabetes treatment from government institutions. The median HbA1c level is 7.9% with range of 5.2% to 16.2%. The study done in Assam by Baishya et al,<sup>[13]</sup> showed that mean HbA1c level was 7.6% with range of 5.9% to 11.7%. The mean value was similar to our study whereas the highest value is higher in our study, which has to be addressed. The study by Dikla et al,<sup>[14]</sup> showed that the mean HbA1c level was 7.8%. Those with diabetic family member have better HbA1c than those who doesn't (p 0.04). Those having weight loss has high HbA1c levels than those who doesn't have weight loss (p 0.005). The study by Wang et al,<sup>[15]</sup> showed that knowledge about diabetes influences HbA1c levels. The study by Dikla et al,<sup>[14]</sup> showed that BMI has association with HbA1c levels.

## CONCLUSION

The study was done with the intent to find the HbA1c levels and factors associated in diabetes mellitus patients. The study showed that the median HbA1c level was 7.9% with range of 5.2% to 16.2%. Among the factors, weight loss and those without family history of diabetes were found to statistically high HbA1c levels. Strategies have to be framed to focus on maintaining the HbA1c levels by adherence to medications and diabetic treatment advice.

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