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ORIGINAL RESEARCH

Correlating HbA1c and dyslipidemia in type 2 diabetes mellitus patients in Kashmiri population: A hospital-based study

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ABSTRACT

Introduction: Dyslipidemia, is one of the major risk factors for macrovascularand microvascular disease in diabetes. Cardiovascular disease, stroke nephropathy and neuropathy, is more common in patients with type 2 diabetes mellitus (T2DM). The relationship between glycated hemoglobin (HbA1c) levels and lipid profiles in patients with type 2 diabetes (T2DM) has been the subject of contradictory research. **Aim**: The study was aimed to assesses the correlation between lipid profile and HbA1c in T2DM patients. **Methodology:** A total of320 subjects were selectedfor the study, among them 160 were T2DM cases and 160 were healthy controls. HbA1c and biochemical and parameters were done on Allinity I Abbott (USA) fully automatic analyzer. **Results:** The comparison of the biochemical profiles of T2DM cases and healthy controls revealed that the former had higher levels of serum Triglycerides (TG), total cholesterol (TC), Low Density Lipoprotein (LDL), and low High-Density Lipoprotein (HDL) than the latter, with a trend that was statistically significant ($p<0.001$). When comparing T2DM cases to healthy controls, the glycemic profile (HbA1c and glucose fasting) was greater in the former group and was determined to be statistically significant ($p<0.001$). **Conclusion:** Our findings verified a strong relationship between HbA1C and TG, TC, LDL and HDL. We observed a substantial variation in the lipid profile between the two HbA1C groups. Nevertheless, glycated hemoglobin may serve as a useful predictor of dyslipidemia in individuals with type 2 diabetes as well as a dependable biomarker of glycemic management.

Keywords: Type 2 diabetes Mellitus, Dyslipidemia, HbA1c, TG, LDL, HDL, Kashmir, Glycemic.

INTRODUCTION

Type II diabetes mellitus (T2DM) is a non-communicable and chronic disorder. Its etiology is multifactorial which progresses slowly[1]. T2DM, is a leading cause of premature deaths worldwide, 90% of people with diabetes have type 2 diabetes (T2DM), the most prevalent kind of the disease [1,2]. If left untreated, T2D can cause serious consequences include retinopathy, coronary heart disease, nephropathy, and neuropathy. According to estimates, the prevalence of diabetes will rise from 4% in 1995 to 5.4% worldwide in 2025 [3]. The World Health Organization (WHO) has estimated that 422 million people worldwide suffer from diabetes, with a prevalence rate of 8.5%. Of those affected, 46.3% are currently undiagnosed, and the figure is expected to increase to 552 million by 2030. Additionally, the largest majority of people in developing nations are between the ages of 40 and 60. In 2017, there were 72 million T2DM patients in India alone; by 2030, that number is expected to increase to 101.2 million [4,5]. Most of the Indian population are unaware about that disease. The risk factors of T2DM is suggestivelyincreased with changing lifestyle, blood pressure,central obesity, inadequate physical activity andunhealthy diet[6].

Blood glucose fasting (FBG), 2hr post prandial blood glucose (2hr-PP) and glycated hemoglobin (HbA1c)

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levels are most widely used as glycemic control markers which indicates progression of the disease and development of its complications. T2DM is reported to be linked with lipid and lipoprotein irregularities, including reduced HDL cholesterol and raised triglycerides [6-8]. The American Diabetes Association (ADA) states that pre-diabetic people may be identified with glycated hemoglobin (HbA1c) levels between 5.7% and 6.4%, however a level of ≥6.5% is diabetes. The low intra-individual variability of the HbA1c level, which is a reflection of the average plasma glucose during the preceding two to three months, as well as the assessment's practicality without requiring fasting, are factors that promote its use in the diagnosis and monitoring of diabetes mellitus [9] . However, because the HbA1c test has a poorer sensitivity in some patient groups (e.g., sickle cell anaemia) or in some populations (e.g., Asian population), it should be used cautiously [10]. Dyslipidemia, also known as atherogenic dyslipidemia, is linked to both macrovascular conditions like heart disease and stroke and microvascular conditions like neuropathy and nephropathy in diabetic individuals [11,12]. High serum levels of triglycerides (TG), low levels of high-density lipoprotein (HDL), and high levels of low-density lipoprotein (LDL) are indicative of atherogenic dyslipidemia [13]. According to certain research, HbA1c may be a useful indicator of heart disease and dyslipidemia [14, 15]. Some studies question the relationship between HbA1c and dyslipidemia, despite the fact that it is used as a measure of glycemic control and related diabetic problems [16-20]. HbA1c and lipid profile were not observed to be significantly correlated in Indian diabetes patients [21]. Furthermore, a mixed bag of research revealed a positive correlation between HbA1c and triglycerides [12,23] and a negative correlation between the two with low-density lipoprotein (LDL) [22].These contradicting findings highlighted the need for further investigations of the association between HbA1c and the lipid profile among diabetic patients. Hence, this study was performed to investigate the association between HbA1c and the lipid profile in a relatively large sample of patients with T2DM in ethnic population of Kashmir.

METHODS

This study was conducted in Government Medical College (GMC) Srinagar at Post Graduate Department of Physiology and Department of Endocrinology, Superspeciality Hospital Srinagar in collaboration with Department of Biochemistry from 2022 to 2024.

Subjects: The 320 subjects were taken for the study. The T2DM cases and healthy controls were enrolled for study from OPD/IPD of Department of Endocrinology, GMC, Srinagar. Among 320 subjects, the 160 T2DM patients were taken for the study and they were diagnosed as per standardAmerican Diabetes Association (ADA) criteria 2018 (table 1) and 160 healthy individuals (age and sex matched) were taken as healthy controls. The study procedure and informed consent were reviewed and sanctioned by the institute ethical committee of GMC, Srinagar. Written informed consent in local (Urdu/Kashmiri) and working language (English) with questionnaire response from patients and healthy controls was documented and record was maintained as per hospital protocol.

Inclusion criteria were: Patients of Kashmiri ethnicity, confirmed cases of T2DM over 2 years.

Exclusion criteria were: Non-Kashmiri origin, patients on lipid medicine, pregnant women, patients suffering from thyroiditis, rheumatoid arthritis, inflammatory bowel syndrome, skin diseases, any cancer and patients < 30 years.

Criteria for Controls: Non-diabetic group (NDM) who had no family history of T2DM and were recruited from hospital undergoing routine health check-ups.

Anthropometric Measurement: Height (cm) was noted by a scale on wall and Weight (kg) was measured by digital weighing machine. The body mass index(BMI) of subjects was calculated by formulae = weight (Kg) / height (m^2). Participants with a BMI ≥30.0 kg/m2 were considered obese as per NCEP ATPIII criteria. "Waist circumference"(WC) was evaluated in the middle, between the lower rib margin and the iliac crest with subjects in upright position.

Criteria for Sample size: Sample size was calculated to detect an effect size of 0.10 at type 1 error of 50% and power of 80% using "G Power version 3.1.9.2". Given the above parameters a total size of 320 (160 in T2DM and 160 in controls in each group) will be sufficient for this study.

Sample collection and separation

5 ml blood was collected by phlebotomists by venipuncture from patients and healthy controls at facility of Government Shri-Maharaja Hari Singh Hospital (SMHS), Srinagar. The patients and healthy controls were recruited from Out-Patient Department (OPD)/ In-Patient Department (IPD) of Department of Endocrinology, GMC, Srinagar. Blood was immediately transferred into 3ml green top heparin vial and 2ml blood into EDTA vial. Heparinized 3ml blood was centrifuged at 4000 RPM for 2 minutes

Biochemical and HbA1c Analysis

Glycated hemoglobin (HbA1c) levels and Biochemistry parameters like Lipid Profile (Triglycerides, Total Cholesterol, Low Density Lipoproteins, High Density Lipoproteins) were

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determined for all patients and healthy controls at the clinical Laboratory of Department of Biochemistry, GMC, Srinagar on Abbott Allinity I analyzer (USA).

Statistical analysis

Data was arrangedon Microsoft excel 2021 spread sheet. All the data were expressed as a mean ± standard deviation and significance value (p) were calculated. Data analysis were performed by using statical'software SPSS 18.1' (Chicago, IL). Students T-test was done on biochemical parameters. Chi-square test was done on socio-demographic characters. Correlation analysis was performed for determining the association of HbA1c and Lipid Profile parameters. For all assessments, $p<0.05$ were considered statistically significant.

Table 1: - American Diabetes Association (ADA) 2018 Criteria for Diagnosing T2DM.

FBG ≥126 mg/dL. **Fasting means no foodingestion for ≥8 hours**
2-hr BG ≥200 mg/dL.
HbA1C ≥6.5%.
Random BG ≥200 mg/dL.

Anthropometric characteristics of cases and controls were summarized in Table 2. A total of three hundred twenty (n=320) subjects were included in the study. Among 320 subjects, one hundred sixty (n=160) were T2DM cases which were diagnosed as per American Diabetes Association (ADA, 2018) criteria and remaining one hundred eighty (n=160) were healthy controls. The risk factors that were taken into consideration included age, gender, lifestyle, body mass index, HbA1c etc.The mean± SDage of T2DM patients were 49.1 ±9.4 Years and that of controls were 48.7±9.4 years which is stastically significant (p=0.004). It was observed that in T2DM patients, mean±SD of BMI was 42.2±6.1 kg/m2 and in healthy controls was 21.2±2.4 kg/m2 which is stastically significant (p=0.002), while there was no significance (p=0.556) found in waist-circumference (WC) within T2DM patients and healthy controls. Among 160 cases 82 were males and 78 females and in healthy controls 95 were males and 85 were females, on gender wise comparison difference in patients and controls are non-significant (p=0.729). Out of 160 T2DM cases, 66 were pre-obese and 28 were obese as compared to controls were stastically significant (p<0.001).

RESULTS

Table 2: Anthropometric analysis of T2DM cases and Controls.

Variables	T2DM Cases (n= 160)	Controls (n=160)	p value (<0.05)
Age (Years)	**49.1±9.4**	**48.7±9.4**	**0.004***
Sex (M/F)	**82/78**	**95/85**	**0.729***
BMI (kg/m2)	**42.2±6.1**	**21.2±2.4**	**0.002***
WC(Inches)	**48.4±4.6**	**28.2±4.5**	**0.556***
BMI (Kg/m^2)			
Underweight	**04**	**1**	
Normal	**62**	**127**	**<0.001**
Overweight	**66**	**18**	
Obese	**28**	**4**	
	00	**02**	

***Data are presented means ± SD. Significance of difference is based on one-Way T-test. p value < 0.05 is stastically significant. "BMI: Body mass index; WC: Waist Circumference"**

Socio-demographic Profile of study group

The socio-demographic profiles of patients are shown in Table 3. Social class scale is based on residence, smoking, lifestyle and education. 43.1% of the T2DM patients were urban and 56.8 % belongs to rural population, while among in healthy controls 41.6 % were urban and 58.3 % belongs to rural population. 31.2 % of the T2DM patients were smokers and 68.7 % were non-smokers, while among healthy controls 2.7 % were smokers and 97.2 % were non-smokers. 31.2 % of the T2DM patients were active and 68.7 % were sedentary, while among healthy controls 58.3 % were active and 41.6 % were sedentary. 36.8 % of the T2DM patients were literate and 63.1 % were illiterate, while among healthy controls 55.0 % were literate and 45.0 % were illiterates.

Table 3: Socio-demographic characteristics of study group.

Variables	Type	Diabetes mellitus n= 160	Percentage	Controls n=160	Percentage	p value (<0.001)
Residence	**Urban**	**69**	**43.1%**	**55**	**34.3 %**	**0.789***
	Rural	**91**	**56.8 %**	**105**	**65.6 %**	
Smoking	**Smoker**	**50**	**31.2 %**	**5**	**3.0 %**	**<0.001***
	Non-Smoker	**110**	**68.7 %**	**155**	**97.0 %**	

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Lifestyle	**Active**	**50**	**31.2 %**	**105**	**65.6 %**	**<0.001***
	Sedentary	**110**	**68.7 %**	**55**	**34.3 %**	
Education	**Literate**	**60**	**36.8 %**	**90**	**56.2%**	**0.001***
	Illiterate	**100**	**63.1 %**	**70**	**43.7 %**	

***Data are presented means ± SD. Significance of difference is based on x^2 test. p value < 0.001 is statistically significant.**

Biochemical Analysis of T2DM Cases and controls

The biochemical profile of T2DM cases and healthy controls was summarized in table 4 and showed that there were increase trend in parameters of lipid profile like serum Triglycerides (TG), total cholesterol (TC), Low Density Lipoprotein (LDL)and low High-Density Lipoprotein (HDL) among T2DM cases as compared to healthy controls and the trend were significantly high ($p<0.05$). The glycemic profile (Fasting glucose and HbA1c) in T2DM cases was higher as compared to healthy controls and are found to be stastically significant ($p<0.05$).

Table 4: Biochemical analysis of the study group.

Variables	T2DM (n= 160)	Controls (n=160)	p value (<0.05)
Glucose Fasting 70-110 (mg/dl)	**171.4±30.5**	**79.9±5.8**	**0.001***
Post-prandial >140 (mg/dl)	**324.2±51.8**	**121.1±9.2**	**0.001***
Cholesterol <200 (mg/dl)	**291.5±49.3**	**111.1±31.8**	**0.001***
Triglycerides <150 (mg/dl)	**321.5±54.3**	**144.1±28.4**	**0.001***
HDL <40 (mg/dl)	**32.4±21.7**	**52.9±11.0**	**0.001***
LDL <100 (mg/dl)	**151.3±8.0**	**69.8±28.9**	**0.001***
HbA1c <5.6-6.5(%)	**9.9±2.7**	**4.6±0.8**	**0.001***

***Data are presented means ± SD. Significance of difference is based on one-Way T-test. p value < 0.05 is stastically significant. HbA1c: Hemoglobin A1C. HDL: High Density Lipoprotein, LDL: Low Density Lipoprotein.**

Table 5 summarize the prevalence of lipid profile and glycemic profile abnormalities in males and females in T2DM cases and it was observed TG: 75.6%, TC: 69.5%, LDL-C: 51.2%, HDL-C: 45.1% in Males and in Females was TG: 67.9%, TC: 74.3%, LDL-C: 42.3%, HDL-C: 48.7%, which was stastically significant in TG and TC (Fig: 1)

Table 5. Frequency analysis of Biochemical Parameters in Males and Females in T2DM Cases.

Parameters	Males N=82	Females N=78	P Value
FBG			
Normal	**00 (0%)**	**00 (0%)**	**<0.001**
High	**82 (100%)**	**78 (100%)**	
HbA1c			
Normal	**05 (6.1%)**	**04 (5.1%)**	**<0.001**
High	**77 (93.9%)**	**74 (94.9%)**	
TG			
Normal	**20 (24.3%)**	**25 (32.0%)**	**<0.001**
High	**62 (75.6%)**	**53 (67.9%)**	
TC			
Normal	**25 (30.4%)**	**20 (25.6%)**	**<0.001**
High	**57 (69.5%)**	**58 (74.3%)**	
LDL-C			
Normal	**40 (48.7%)**	**45 (57.6%)**	**0.785**
High	**42 (51.2%)**	**33 (42.3%)**	
HDL-C			**0.565**

DOI: 10.69605/ijlbpr_13.8.2024.74

Normal **Low**	**45 (54.8%)** **37(45.1%)**	**50 (64.1%)** **38 (48.7%)**	

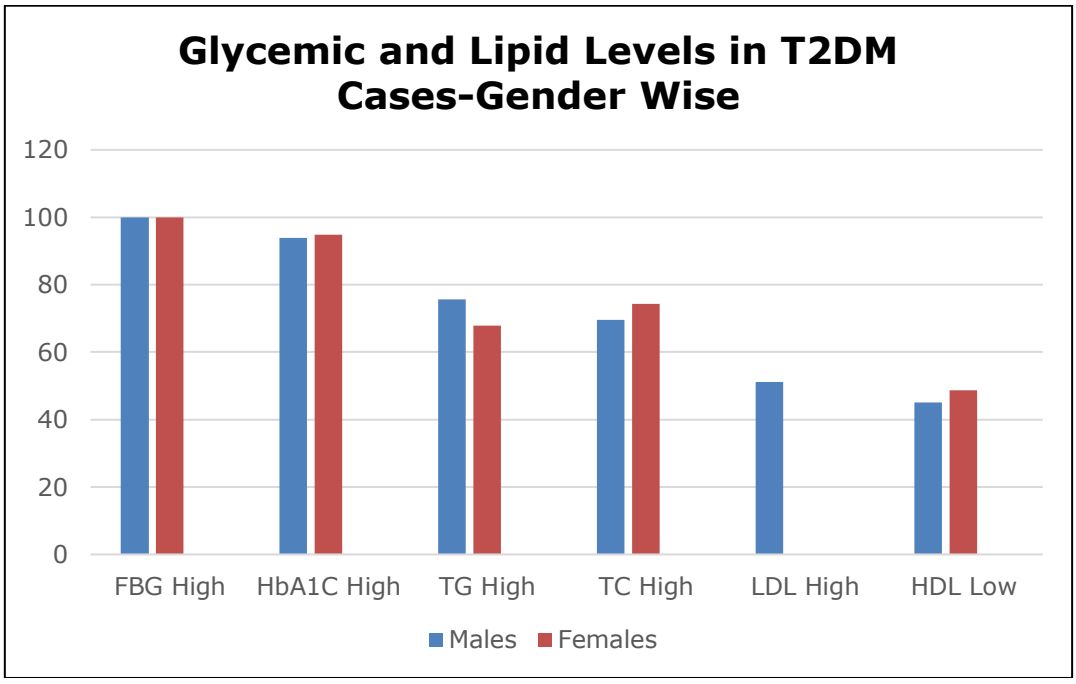

Figure 1: Histogram showing levels of HbA1c and Lipids in Males and Females in T2DM.

Comparison of glycemic control between groups

To assess the effect of glycemic control on different lipid parameters, all T2DM patients were divided into two groups based on their glycemic index: patients with good glycemic control (HbA1C value ≤ 7.0%) and patients with poor glycemic control (HbA1C value >7.0%) were included in the first group (Table 5). Duration of diabetes and glucose management had a statistically significant relationship (p≤0.001). Table 6 shows that patients with poor glycemic control had substantially higher values of FBG 123±15.5 vs 210±18.5; p≤0.001), TC 175±25.5 vs 201±30.5; p≤0.001), and TG 120±30.5 vs 145±30.5; p≤0.001) compared to those with good glycemic control.

Table 6: Comparison of Bio-clinical and lipid parameters between the good and poor glycemic control groups according to HbA1C value.

Parameters	T2DM, N=160		P-Value
	Good Glycemic Group-I HbA1c <7%.	Poor Glycemic Group-II HbA1c >7%.	
Age (years)	**54.6±11.2**	**51.9±10.4**	**<0.001**
Durationof T2DM **<5years** **>5 years**	 **40 (25%)** **30 18.7%)**	 **40 (25.0%)** **50 (31.2%)**	**0.001**
Physical activity **Yes** **No**	 **55 (34.3%)** **25 (15.6%)**	 **25 (15.6%)** **55 (34.3%)**	**<0.005**
Systolic Blood Pressure (mm/Hg)	**145±4.5**	**152±2.5**	**0.003**
Diastolic Blood Pressure (mm/Hg)	**88±3.5**	**90±2.5**	**0.004**
Fasting Blood Sugar **70-110 mg/dl**	**123±15.5**	**210±18.5**	**<0.001**
Total Cholesterol **<200 mg/dl**	**175±25.5**	**201±30.5**	**<0.001**
Triglycerides **<150 mg/dl**	**120±30.5**	**145±20.5**	**<0.001**
HDL **<40 mg/dl**	**45±11.5**	**42±5.5**	**0.0871**
LDL **<100 mg/dl**	**102±14.5**	**125±10.5**	**0.0475**

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Correlation of Lipid Profile Parameters with glycemic profile, Gender-wise in Cases and Controls

The results of our study showed a highly significant correlation between HbA1C, and FBG Males (r= 0.456, p≤ 0.001), and TG (r=0.849, p ≤ 0.001) in females FBG (r= 0.536, p≤ 0.001), and TG (r=0.873, p ≤ 0.001). However, no significant correlation was found between HDL-C (r=0.304, p=0.714), LDL-C (r=0.001, p=0.863), and HbA1C (Table 7).

Table 7: Correlation of Lipid Profile Parameters with glycemic profile, Gender-wise in Cases and Controls.

Parameters	Cases				Controls			
	HbA1c		Fasting Glucose		HbA1c		Fasting Glucose	
	Males n=82	Females n=78	Males n=82	Females n=78	males n=95	females n= 85	males n=95	females n= 85
Total Cholesterol	*p=0.002 *r=0.849	p=0.004 r=0.873	p=0.005 r=0.456	p=0.005 r=0.536	*p=0.035 *r=0.328	p=0.010 r=0.358	p=0.012 r=0.259	p=0.053 r=0.210
Triglycerides	p=0.001 r=0.730	p=0.004 r=0.874	p=0.003 r=0.778	p=0.001 r=0.611	p= 0.145 r= 0.162	p=0.082 r=0.188	p=0.829 r=0.023	p=0.830 r=0.023
HDL	p=0.714 r=0.304	p=0.863 r=0.001	p=0.971 r=0.004	p=0.723 r=0.041	p=0.238 r=0.021	p=0.011 r=0.365	p=0.743 r=0.034	p=0.044 r=0.218
LDL	p=0.324 r=0.137	p=0.811 r=0.027	p=0.033 r=0.238	p=0.905 r=0.014	p=0.050 r=0.631	p=0.041 r=0.221	p=0.433 r=0.082	p=0.660 r=0.048

DISCUSSION

The number of people with type 2 diabetes (T2DM) worldwide is expected to rise from 415 million at present to 642 million by 2040. It has been observed that the number of T2DM patients is rising in all emerging nations, and that 75% of T2DM patients reside in these nations. Numerous lipid abnormalities are a result of diabetes, a complex disease. The connection between diabetes and cardiovascular disorders is well-established, and in recent years, there has been much discussion about it. It has been demonstrated that diabetes mellitus and dyslipidemia are both reliable indicators of metabolic diseases, cardiovascular disease, and hyperinsulinemia. In this study, we aimed to determine the prevalence of dyslipidemia and to examine the association between HbA1C, lipid profile patients with T2DM. This cross-sectional study was conducted on 160 T2DM patients and 160 healthy controls. The increased risk of cardiovascular disease (CVD) in T2DM patients is partly due to the abnormalities in the lipid profile accompanying T2DM. Various studies have reported the association between HbA1c and one or more parameters of the lipid profile in T2DM patients, and some studies suggested HbA1c as a possible biomarker for recognizing the abnormal lipid profile of T2DM patients and for identifying the T2DM patients at risk of CVD [23-25]. According to our findings, there is a strong positive association between HbA1c and both total cholesterol and triglycerides. These results are consistent with some other research that found a strong positive connection between HbA1c and one or more lipid profile parameters in patients with type 2 diabetes.[26,27]. Our results and the previous reports highlight the important link between glycemic control and dyslipidemia [23-28]. This indicates that HbA1c is directly associated with dyslipidemia in T2DM diabetic patients and indirectly helps in assessing the risk of micro- and macrovascular problems [29].

When dyslipidemia occurs in T2DM patients, insulin resistance is thought to be the cause. Increased TG levels in T2DM patients are believed to be associated with insufficient insulin secretion or function through a number of mechanisms [30]. However, the current investigation found no statistically significant connection between HbA1c,LDL-c and HDL-c. These findings are in line with some past research that also found no link between these factors, but they are at odds with other findings.[22-30].The most common dyslipidemiaamong T2DM patients (54.1%) in the current study was LDL-c, while abnormal HbA1c was detected in 94.9% of the patients. These findings are consistent with a few earlier research projects on dyslipidemia in patients with diabetes [31]. Nonetheless, in contrast to our findings, a number of previous investigations have found that diabetes patients with high LDL-clevels are less likely to have them[32–36]. There are several possible reasons for this discrepancy, such as variations in the study design, the study population chosen, and regional variations. This suggests that dyslipidemia may develop due to causes other than type 2 diabetes. When comparing the two genders, it was found that the HbA1c, total cholesterol, and low HDLvalues were significantly higher in the female population. Such findings have not been reported by many other research [37]. Our findings and those of other studies do, however, differ in a few ways [38]. Changes in body lipid distribution caused by sex hormones may account for gender-related variations in lipid parameters, which in turn affect lipoprotein levels [39].Our T2DM cases were obese, as shown by a mean BMI > 30. It has previously been reported [40] that poor blood sugar regulation is associated with obesity and physical inactivity.The lipid profile parameters for TC

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(5.49±0.04 vs. 5.16±0.03 mmol/L), TG (2.13±0.04 vs. 1. 88±0.02 mmol/L), HDL-c(1.1±0.01 vs. 1.21±0.08 mmol/L), and LDL-c(3.34±0.02 vs. 3.09±0.03 mmol/L) were increased in the group of patients with poor glycemic control, according to a study by Khan et al. [41]. The relative stability of HbA1C may be the reason for these contradictory findings. In fact, throughout time, HbA1C levels stay unchanged but lipid profiles and FBG levels fluctuate quickly. With a larger sample size, more research on the glycemic profile and lipid profiles in T2DM patients,will further increase the reliability of the association found.

CONCLUSION

The study's findings indicate a strong relationship between HbA1C and a number of circulating lipid markers. As a result, we observed a substantial variation in the lipid profile between HbA1C groups. The group with HbA1c >7% were having high TG, Cholesterol and high LDL as compared to HbA1c<7%.Nevertheless, glycated hemoglobin may serve as a useful predictor of dyslipidemia in individuals with type 2 diabetes as well as a dependable biomarker of glycemic management. Therefore, in order to lower the risk of developing cardiovascular diseases, it is highly suggested that individuals, with HbA1c>7% to have continuous monitoring of lipid profile.

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