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A Study of Glycemic, Insulinemic and Lipidemic Abnormalities in Controlled *vs.* Uncontrolled T2dm with Particular Reference to Hba1c% Level

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Abstract

Objective: The global incidence of diabetes is escalating at an alarming rate. This study aims to compare glycemic control, insulin resistance, lipid profiles, and serum creatinine levels in individuals with controlled and uncontrolled diabetes and assess clinical parameters based on the duration of uncontrolled diabetes.

Methods: A cross-sectional study was conducted on 357 individuals with T2DM aged 40–60 years. Participants were divided into two groups based on HbA1c% levels: controlled diabetes (HbA1c ≤ 7.0%, n=143) and uncontrolled diabetes (HbA1c>7.0%, n=214). Further subdivision categorized subjects by disease duration: short-term (<5 years) and long-term (>5 years). Fasting Blood Glucose (FBG), insulin, HbA1c%, triglycerides, total cholesterol, HDL-C, LDL-C, and creatinine levels were measured using standardized techniques. Indices such as HOMA B%, HOMA S%, HOMA IR, QUICKI, and Sr HOMA were calculated using appropriate methods. Statistical analyses were performed using independent t-tests and Fisher's exact test, with significance set at $p < 0.05$.

Results: BMI ($p=0.05$), FBG ($p<0.001$), HOMA IR ($p<0.05$), TG ($p<0.005$), T Chol ($p<0.05$), and LDL ($p<0.001$) level were significantly higher in uncontrolled DM in compared to controlled DM subjects, respectively. Whereas, Sr HOMA ($p<0.05$) was significantly lower in uncontrolled DM than in the control DM group. A high degree of positive correlation of HbA1C% with FBG ($r=0.298$, $p<0.001$) and GIR ($r=0.166$, $p<0.05$) was found, as well as a significant ($r= -0.164$, $p<0.05$) negative correlation was found with HOMA B% in uncontrolled DM subjects respectively. However, HOMA B% and Sr HOMA significantly ($p<0.05$, both) decreased, and HOMA S% significantly ($p<0.05$) increased in uncontrolled DM subjects who had a longer duration of DM. Serum creatinine level was significantly higher in uncontrolled DM compared to the controlled DM subjects.

Conclusion: FBG, insulin resistance, and lipid parameters were elevated in uncontrolled diabetic subjects, which may lead to the impairment of renal function.

Keywords: T2DM • HbA1c% • Glucose • Insulin • Lipid profiles • Creatinine

Introduction

Diabetes Mellitus (DM) encompasses a spectrum of metabolic disorders characterized by persistent hyperglycemia, resulting from diminished insulin secretion, impaired glucose utilization, and excessive glucose production. These metabolic imbalances lead to secondary complications across various organ systems, including neuropathy, nephropathy, retinopathy, cardiovascular and cerebrovascular diseases and diseases related to peripheral vessels and others [1]. Individuals with diabetes face an elevated risk of severe health outcomes such as myocardial infarction, stroke, renal failure, and vision loss, especially with prolonged disease duration.

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Haemoglobin A1c (HbA1c) serves as a reliable indicator of average blood glucose levels in fasting and postprandial states and is widely employed for monitoring chronic glycaemia in diabetes management [2]. Insulin resistance, a hallmark of Type 2 Diabetes Mellitus (T2DM), has long been associated with obesity, metabolic syndrome, hypertension, and cardiovascular diseases [3,4]. HbA1c levels are also considered a key marker for assessing glycaemic control and cardiovascular risk, with studies indicating an 18% increase in Cardiovascular Disease (CVD) risk for every 1% rise in HbA1c levels [5-8].

Moreover, impaired insulin function and relative insulin deficiency disrupt plasma lipid profiles, increasing the risk of atherosclerosis and coronary artery disease [9]. Research suggests a significant relationship between HbA1c and lipid markers such as Total Cholesterol (TC), Low-Density Lipoprotein (LDL), and Triglycerides (TGs) [10-13]. Although some studies report no association [14]. This study aims to evaluate Fasting Blood Glucose (FBG), fasting insulin, HbA1c, lipid profiles, and serum creatinine in diabetic patients. It also seeks to compare insulin indices and lipid profiles between controlled and uncontrolled diabetes groups while examining complications based on diabetes duration.

Materials and Methods

Study subject

It was a cross-sectional prospective study. Three fifty-seven Bangladeshi

T2DM subjects were randomly enrolled from the OPD of a tertiary care hospital. Subjects were classified according to HbA1c% level (controlled T2DM group HbA1c≤7.0%: 143 subjects and uncontrolled group HbA1c>7.0%: 214 Subjects) [15]. The objectives of the study were explained to the participants. Before participating in the study, each patient gave informed written consent and a questionnaire covering physical and clinical information. The institutional ethical committee approved the protocol for conducting the study according to the declaration of WMA (2013) [16].

Subjects' selection criteria

The inclusion criteria for the subjects were type 2 DM subjects aged 30-60 years and using oral hypoglycaemic agents. Exclusion criteria were subjects treated with insulin, evidence of hepatic dysfunction, renal failure, the presence of malabsorption syndrome, and pregnancy.

Collection of sample

Approximately 6.0 mL of blood was collected from each subject, 2.0 mL of which was transferred to an EDTA tube for HbA1c% analysis and 4.0 mL in a vacutainer tube for biochemical tests. Serum was collected after centrifugation at 3000 rpm for 10 min. Tubes were stored at -200 C until further use.

Biochemical assessments

The levels of serum Fasting Blood Glucose (FBG), HbA1c, triglycerides, total cholesterol, HDL-C, LDL-C, and creatinine were determined using standardized techniques. Fasting insulin levels were measured using Enzyme-linked Immunosorbent Assay (ELISA). The parameters HOMA B%, HOMA S%, and HOMA IR were computed using HOMA-SIGMA software (version 2.2), while QUICKI and Secretory HOMA were derived using established formulas.

Statistical data analysis

The data were expressed as mean ± Standard Deviation (SD). Differences between values were assessed for statistical significance using the Independent Samples T-Test, performed with the Statistical Package for the Social Sciences (SPSS), version 22. Fisher's exact test was conducted using Graph Pad Prism, version 5. A p-value of <0.05 was considered statistically significant.

Results

Based on the HbA1c% value, subjects were categorized into 2 categories: controlled (HbA1c% <7) and uncontrolled (HbA1c% >7) (ADA, 2020). Among the enrolled T2DM subjects, 40% had controlled and 60% had uncontrolled T2DM (Table 1). As expected, the mean±SD of the HbA1c% value was significantly higher (p<0.001) in uncontrolled DM compared to controlled DM subjects (Table 1).

Results are presented as mean ± Standard Deviation (SD). Data were compared using the Independent Sample T-Test. *p<0.001.

(Table 2) compares basic characteristics among controlled and uncontrolled diabetic patients. BMI was significantly higher in uncontrolled DM subjects compared to control DM (p=0.05), and the uncontrolled DM group had a higher family history of diabetes (p=ns) (Table 2).

Results are presented as mean ± Standard Deviation (SD). Groups of data were compared using an independent Sample T Test. Fisher's exact test was performed to explore the association between groups. Differences were considered significant at p<0.05. NS= Not significant

(Table 3) shows the glycemic, insulinemic, and lipidemic status of the two groups of DM subjects. It was found that FBG (p<0.001), HOMA IR (p<0.05), TG (p<0.005), T Chol (p<0.05), and LDL (p<0.001) levels were significantly higher in uncontrolled compared to controlled DM subjects respectively. On the other hand, Sr HOMA (p<0.05) was significantly lower in uncontrolled than control DM subjects (Table 3).

Results are presented as mean ± standard deviation (SD). Groups of data were compared using the Independent Sample T-Test. Differences were considered significant at p<0.05. NS= Not significant

The correlation coefficient of HbA1c% with FBG, fasting insulin, GIR, HOMA B%, HOMA S%, Insulin resistance (HOMA IR), QUICKY, Sr HOMA, triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, and S creatinine were found in both controlled and uncontrolled DM subjects. A high degree of statistically significant positive correlation of HbA1c% level with FBG (r=0.298, p<0.001) (Figure 1) and GIR (r=0.166, p<0.05) (Figure 3) was found. A negative correlation was found with HOMA B% (r= -0.164, p<0.05) (Figure 2) in uncontrolled DM subjects, respectively, whereas no significant correlations were observed among other clinical parameters with HbA1c% level in that group (Data not shown) (Figures 1-3).

The clinical parameters between controlled and uncontrolled DM subjects according to the duration of diabetes are presented in (Table 4). The subjects of both groups were subdivided according to the duration of diabetes (short-term duration of 5 years and long-term duration of more than 5 years). Body fat in kg was significantly (p<0.05) lower, and HbA1c% was significantly (p<0.05) higher in long-term duration uncontrolled DM subjects. There was a significant decrease in HOMA B% (p<0.05) and Sr HOMA (p<0.05) and a significant (p<0.05) increase in HOMA S% in long-term duration uncontrolled DM subjects. On the other hand, serum creatinine level was significantly (p<0.05) higher in uncontrolled DM subjects with long-term duration of diabetes. Lipid profiles did not find any significant differences (Data not shown) (Table 4).

Table 1. Categorizing T2DM subjects as controlled and uncontrolled DM based on HbA1c% value.

T2DM Subjects (n=357) (M ± SD)	HbA1c (%)	p-value
Controlled DM (n=143, 40%)	6.3 ± 0.5	<0.001
Uncontrolled DM (n=214, 60%)	8.4 ± 1.1	

Table 2. Basic characteristics of the control and uncontrolled DM subjects.

Variables	T2D Subjects (n=357)		p-value
	Controlled DM (n=143)	Uncontrolled DM (n=214)	
Age (year)	50.0 ± 11.0	49.0 ± 10.0	NS
BMI (kg/m^2)	24.9 ± 3.4	25.5 ± 4.1	0.05
Waist: Hip ratio	1.0 ± 0.2	1.0 ± 0.1	NS
Body fat (kg)	30.8 ± 8.2	30.8 ± 7.5	NS
SBP (mmHg)	121.0 ± 12.0	121.0 ± 12.0	NS
DBP (mmHg)	78.0 ± 8.0	78.0 ± 6.0	NS
Family History of DM (Yes)	92	116	NS

Table 3. Comparison of glycemic, insulinemic and lipidemic status between controlled and uncontrolled diabetes patients.

Parameters	T2DM Subjects (n=357)		p-value
	Controlled (n=143)	Uncontrolled (n=214)	
FBG (mmol/L)	6.4 ± 1.7	8.2 ± 2.8	<0.001
Fasting Insulin (IU/L)	22.16 ± 12.88	24.38 ± 14.79	NS
GIR	0.39 ± 0.29	0.44 ± 0.29	NS
HOMA B%	138.4 ± 81.9	103.8 ± 76.4	NS
HOMA S%	45.5 ± 29.0	39.5 ± 21.4	NS
HOMA IR	2.89 ± 1.56	3.34 ± 1.88	<0.05
QUICKY	0.30 ± 0.02	0.29 ± 0.02	NS
Sr HOMA	258.3 ± 360.3	176.1 ± 218.3	<0.05
Serum Triglycerides (mg/dl)	132 ± 64	164 ± 86	<0.005
Total Cholesterol (mg/dl)	160 ± 45	162 ± 62	<0.05
LDL Cholesterol (mg/dl)	90 ± 34	90 ± 57	<0.001
HDL Cholesterol (mg/dl)	40 ± 9	40 ± 11	NS
Serum Creatinine (mg/dl)	0.89 ± 0.20	0.89 ± 0.18	NS

Table 4. Clinical parameters between controlled and uncontrolled DM subjects according to duration of diabetes.

Parameters	Controlled DM (n=143)			Uncontrolled DM (n=214)		
	Short Term (<5yrs)	Long Term (>5yrs)	p-value	Short Term (<5yrs)	Long Term (>5yrs)	p-value
Body fat (kg)	n=101	n=42	NS	n=147	n=67	<0.05
HbA1c%	20.2 ± 5.6	20.5 ± 12.0	NS	21.3 ± 9.1	19.1 ± 5.0	<0.001
HOMAB%	6.3 ± 0.5	6.2 ± 0.8	NS	8.3 ± 0.9	8.7 ± 1.5	<0.05
HOMAS%	136.3 ± 2.1	143.4 ± 71.6	NS	110.3 ± 85.5	89.3 ± 47.9	<0.05
Creatinine (mg/dl)	44.8 ± 31.8	47.2 ± 21.2	NS	39.0 ± 22.0	40.7 ± 19.9	<0.05

Results are presented as mean ± Standard Deviation (SD). Groups of data were compared using the Independent Sample T Test. Differences were considered significant at p<0.05.

Discussion

A total of 357 subjects were included in the present study (male: female-170:193). They are considered as controlled (HbA1c%: 6.3%±0.5) and uncontrolled (HbA1c%: 8.4%±1.1) T2DM according to their HBA1c% level (Table 1). This study revealed that BMI was significantly higher in uncontrolled DM subjects (p=0.05) compared to controlled (Table 2). Rodbard HW, et al. [17] observed that T2DM subjects had an increased risk of disability due to associated glycemic and lipidemic complications like Coronary Artery Disease (CAD), Cardiovascular Disease (CKD), etc. The present study revealed that FBG (p<0.001), TG (p<0.005), T Chol (p<0.05), and LDL (p<0.001) levels were significantly higher in uncontrolled DM than controlled DM subjects which correlate with others [14,18-22] HOMA IR (p<0.05) was higher, and Sr HOMA (p<0.05) was lower significantly in uncontrolled than controlled DM (Table 3) that cannot correlated with other authors.

A high degree of positive correlation of HbA1c% with FBG (r=0.298, p<0.001) was found in uncontrolled DM subjects (Figure 1), which is in line with the observation by Soundarya T and Kumar PA [23]. There was a high degree of positive correlation of HbA1c% with GIR (r=0.166, p<0.05) (Figure 2) as well as a significant (r=-0.164, p<0.05) negative correlation with HOMA B% (Figure 3) found in uncontrolled DM subjects respectively. There was no correlation between HbA1c% and lipids, which also correlates with the results of Soundarya T and Kumar PA [23] and Majumder M, et al. [24]. However, other investigators found opposite results [20,25,26] (Table 4).

Several studies revealed that micro- and macrovascular complications are related to the duration of diabetes [27-29]. In this study, some clinical parameters were measured in controlled and uncontrolled DM subjects based on short-term and long-term duration of diabetes. It was found that uncontrolled

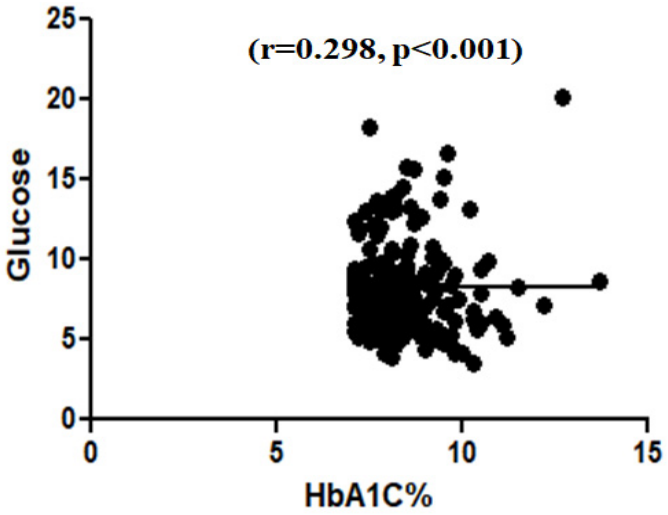

Figure 1. Correlation of HbA1c% with glucose.

DM subjects with a long-term duration of diabetes (>5 yrs) showed a significant (p<0.05) decrease in BMI. That may be associated with muscle wasting (with decreased insulin sensitivity, the process of protein synthesis is less effective) for the long-term duration of uncontrolled diabetic subjects. However, HOMA B% and Sr HOMA were decreased, and as well as HOMA S% was increased significantly (p<0.05) in the long-term duration of the uncontrolled DM subjects than the short-term duration of uncontrolled DM (Table 4).

Those findings were similar to those of Wysham C and Shubrook J [30], where the investigators concluded that significant beta-cell dysfunction is associated with a long duration of diabetes and high HbA1C% level. It is well established that CKD is one of the long-term micro vascular complications of diabetes. An Ethiopian hospital-based study revealed that a significant

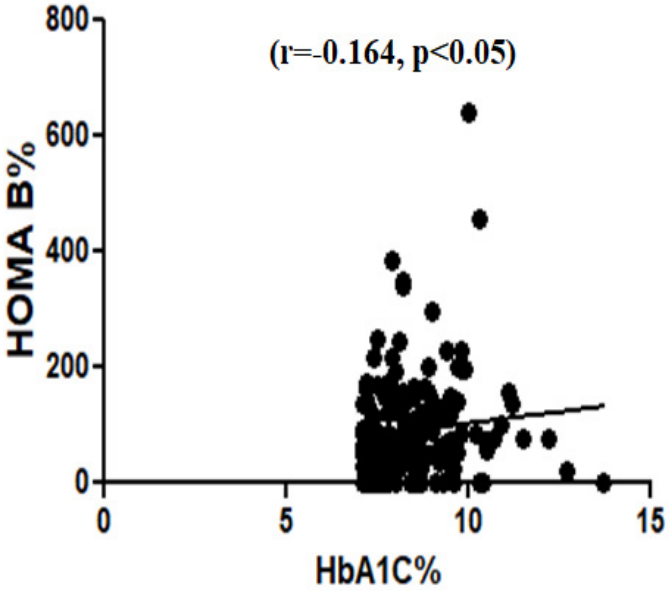

Figure 2. Correlation of HbA1c% with HOMA B%.

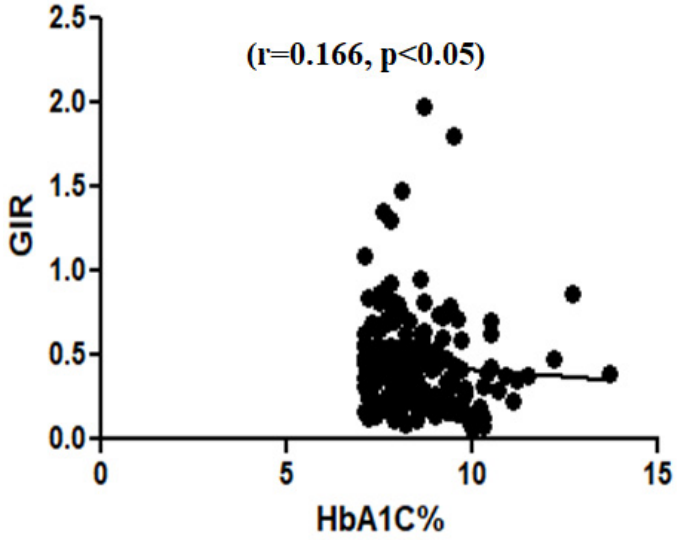

Figure 3. Correlation of HbA1c% with GIR.

Table 4. Clinical parameters between controlled and uncontrolled DM subjects according to duration of diabetes.

Parameters	Controlled DM (n=143)			Uncontrolled DM (n=214)		
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HOMAB%	6.3 ± 0.5	6.2 ± 0.8	NS	8.3 ± 0.9	8.7 ± 1.5	<0.05
HOMAS%	136.3 ± 2.1	143.4 ± 71.6	NS	110.3 ± 85.5	89.3 ± 47.9	<0.05
Creatinine (mg/dl)	44.8 ± 31.8	47.2 ± 21.2	NS	39.0 ± 22.0	40.7 ± 19.9	<0.05

proportion of diabetic subjects found a continuous increase in serum creatinine levels within five years compared with the baseline level [31]. In the present study, we have also found that serum creatinine level was significantly higher in uncontrolled DM subjects with long-term duration of diabetes, which coincides with the above finding.

Conclusion

Elevated glucose, insulin resistance, decreased secretory HOMA, and elevated lipid status in uncontrolled diabetic subjects may increase the risk of diabetic complications, which is also associated with the duration of diabetes. Therefore, blood glucose and HbA1c% should be kept within the recommended target range to attain higher life expectancy.

Data Availability Statement

All relevant data are available at Dhaka University Institutional Repository,

URI:http://repository.library.du.ac.bd:8080/xmlui/xmlui/handle/123456789/1716

Author Contributions

Begum Rokeya: conceived the idea for the research; Amrita Bhowmik conducted the practical part, wrote the manuscript, and also made substantial contributions to the conception and design, analysis, and interpretation of data. Mossihuzzaman Mohammad provided partial financial support, and Laboratory opportunities. Begum Rokeya and Yearul Kabir have been involved in supervising the work, revising the manuscript, financial support, and Laboratory opportunities. All authors checked and approved the final version of the manuscript.

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Conflict of interest

The authors report no conflict of interest.

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