Section: General Medicine/ Biochemistry

Original Research Article

INVESTIGATING THE CORRELATION BETWEEN SERUM BIOMARKERS AND DISEASE SEVERITY IN TYPE 2 DIABETES MELLITUS: AN OBSERVATIONAL STUDY

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a prevalent chronic disease. This study investigates the correlation between various serum biomarkers and disease severity to better understand disease progression.

Material and Methods: An observational study was conducted with 100 T2DM participants (52 males, 48 females) aged 40-70. Participants were classified into mild, moderate, and severe categories based on clinical evaluation. Serum biomarkers such as fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), C-reactive protein (CRP), lipid profile, serum creatinine, and microalbuminuria were measured. The correlation between each biomarker and disease severity was assessed using Pearson's correlation coefficients.

Results: Significant positive correlations were observed between FPG ($r = 0.68$, $p < 0.001$), HbA1c ($r = 0.72$, $p < 0.001$), CRP ($r = 0.54$, $p < 0.01$), triglycerides ($r = 0.58$, $p < 0.01$), serum creatinine ($r = 0.48$, $p < 0.01$), and microalbuminuria ($r = 0.63$, $p < 0.001$) with disease severity. In contrast, HDL cholesterol was inversely correlated ($r = -0.37$, $p < 0.05$) with severity. Higher levels of these biomarkers were associated with greater disease progression from mild to severe.

Conclusion: The study identifies significant correlations between T2DM disease severity and key serum biomarkers. Elevated levels of FPG, HbA1c, CRP, triglycerides, serum creatinine, and microalbuminuria indicate increased disease severity. Conversely, HDL cholesterol is inversely associated. These biomarkers provide critical insights into disease progression and can aid in risk stratification and targeted intervention.

Keywords: Type 2 diabetes mellitus, fasting plasma glucose, glycated hemoglobin, C-reactive protein, lipid profile.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and impaired insulin secretion, leading to persistent hyperglycemia.[1,2] It is one of the fastest-growing health challenges worldwide, with an increasing prevalence due to lifestyle changes and aging populations.[3] Uncontrolled T2DM is associated with numerous complications, including cardiovascular disease, nephropathy, neuropathy, and retinopathy, significantly impacting morbidity and mortality rates.[4]

The early detection and management of T2DM are crucial for preventing the progression of complications.[5] Understanding the correlation between various serum biomarkers and disease

severity can provide valuable insights into the progression of T2DM, guiding personalized interventions and risk stratification.[6]

Several serum biomarkers, including fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), C-reactive protein (CRP), and lipid profiles, are well-established indicators of glycemic control and systemic inflammation in diabetic patients.[7] Additionally, serum creatinine and microalbuminuria are critical markers of renal function, often affected in T2DM due to diabetic nephropathy. Each of these biomarkers provides insights into the different aspects of disease progression.[8]

This study aims to investigate the relationship between these key serum biomarkers and disease severity in T2DM patients. By evaluating these correlations, we can enhance our understanding of T2DM progression, enabling clinicians to identify high-risk individuals, tailor interventions more effectively, and improve overall disease management.

MATERIAL AND METHODS

Study Design and Setting

This observational study was conducted at the RVM Institute of Medical Sciences and Research Center, located in Laxamakkapally, Siddipet District, from February 2023 to January 2024. The research aimed to investigate the correlation between various serum biomarkers and disease severity in type 2 diabetes mellitus (T2DM).

Study Population

A total of 100 participants with clinically confirmed T2DM were enrolled. The cohort included 52 males and 48 females aged between 40 and 70 years. Patients were categorized into mild, moderate, or severe T2DM groups based on their clinical profiles and glycemic control.

Inclusion Criteria

- Confirmed diagnosis of T2DM.
- Age range of 40 to 70 years.

Exclusion Criteria

- Type 1 diabetes mellitus.
- Pregnant women.
- Any known systemic illnesses that could affect biomarker levels.

Data Collection and Laboratory Assessment

Demographics and Clinical Data: Information including age, gender, and disease severity was collected.

Biomarker Analysis: Fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), C-reactive protein (CRP), serum creatinine, and microalbuminuria were measured using standardized laboratory procedures. Lipid profiles (total cholesterol, triglycerides, and HDL cholesterol) were also assessed.

Disease Severity Classification: Disease severity was classified based on clinical criteria and HbA1c levels into mild, moderate, and severe categories.

Statistical Analysis

Pearson's correlation coefficients were used to assess the relationship between serum biomarkers and disease severity. Results were considered statistically significant at p-values < 0.05. Data were analyzed using statistical software, and descriptive statistics were reported as mean ± standard deviation (SD).

Ethical Considerations

The study was conducted in accordance with ethical guidelines and standards. Informed consent was obtained from all participants. The study protocol was reviewed and necessary prior permissions taken from concerned authorities.

RESULTS

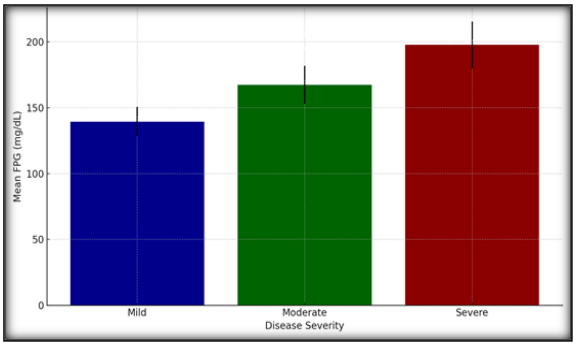

Figure 1: Correlation between Fasting Plasma Glucose (FPG) and Disease Severity

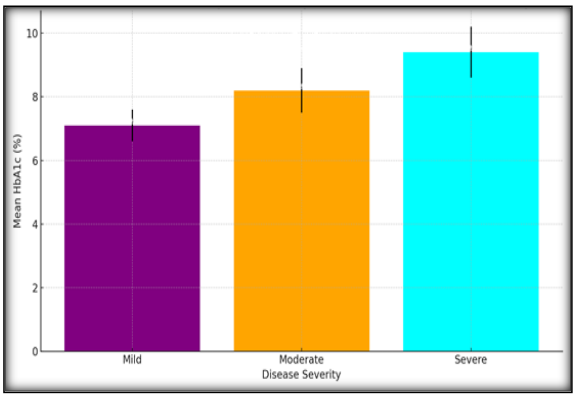

Figure 2: Correlation between Glycated Hemoglobin (HbA1c) and Disease Severity

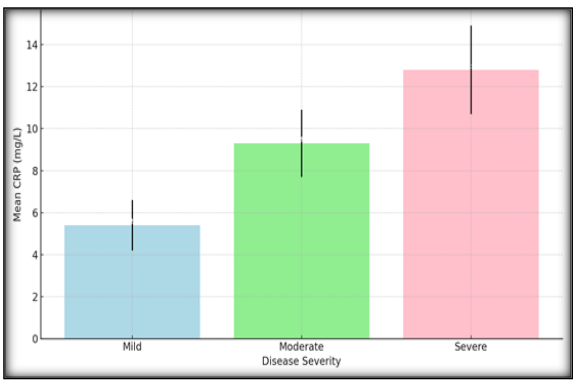

Figure 3: Correlation between C-Reactive Protein (CRP) and Disease Severity

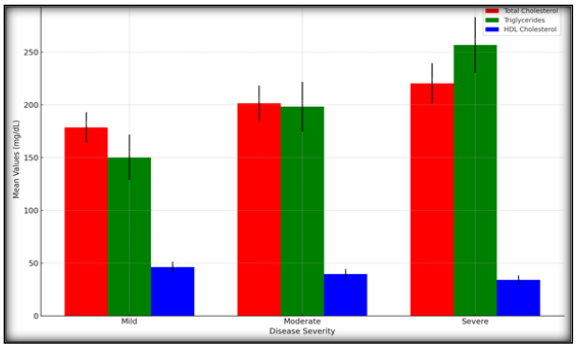

Figure 4: Correlation between Lipid Profile and Disease Severity

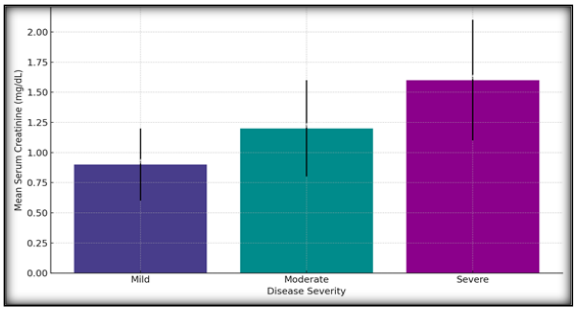

Figure 5: Correlation between Serum Creatinine and Disease Severity

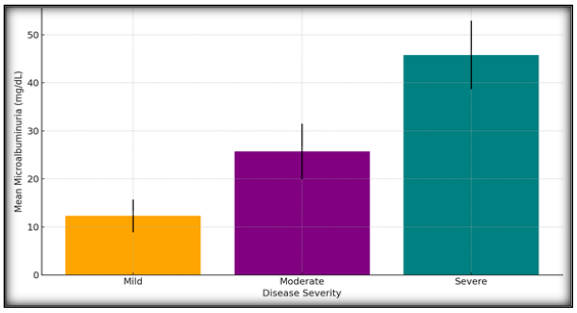

Figure 6: Correlation between Microalbuminuria and Disease Severity

This observational study analyzed the relationship between serum biomarkers and disease severity in type 2 diabetes mellitus across a sample of 100 participants (Table 1). The cohort consisted of 52 males and 48 females, with an average age of 56.3 ± 8.4 years (age range: 40-70 years).

Fasting Plasma Glucose (FPG): The correlation between FPG levels and disease severity was significant (Table 2). Mean FPG levels for mild, moderate, and severe groups were 139.4 ± 11.2 mg/dL, 167.3 ± 14.5 mg/dL, and 197.6 ± 17.6 mg/dL, respectively. The correlation coefficient ($r = 0.68$) was significant ($p < 0.001$), indicating a positive relationship between higher FPG levels and disease severity.

Glycated Hemoglobin (HbA1c): HbA1c also correlated positively with disease severity (Table 3). Mean HbA1c values increased from mild (7.1 ± 0.5%) to moderate (8.2 ± 0.7%) to severe (9.4 ± 0.8%) disease. The correlation coefficient ($r = 0.72$) was significant ($p < 0.001$), indicating a strong correlation.

C-Reactive Protein (CRP): Inflammatory marker CRP was positively correlated with disease severity (Table 4). Mean CRP levels were 5.4 ± 1.2 mg/L (mild), 9.3 ± 1.6 mg/L (moderate), and 12.8 ± 2.1 mg/L (severe). The correlation coefficient ($r = 0.54$) was significant ($p < 0.01$), showing that CRP levels increase with worsening disease.

Lipid Profile: The lipid profile showed significant correlations with disease severity (Table 5). Total cholesterol levels rose with disease severity ($r = 0.42$, $p < 0.05$). Triglycerides also correlated significantly ($r = 0.58$, $p < 0.01$), increasing from 150.3 ± 21.4 mg/dL in the mild group to 256.8 ± 26.1 mg/dL in the severe group. HDL cholesterol showed a significant negative correlation with severity ($r = -0.37$, $p < 0.05$), decreasing as disease severity increased.

Serum Creatinine: Serum creatinine levels were positively correlated with disease severity (Table 6). The mean values were 0.9 ± 0.3 mg/dL (mild), 1.2 ± 0.4 mg/dL (moderate), and 1.6 ± 0.5 mg/dL (severe), with a significant correlation coefficient ($r = 0.48$, $p < 0.01$).

Microalbuminuria: Microalbuminuria correlated positively with disease severity (Table 7). Mean values increased from 12.3 ± 3.4 mg/dL (mild) to 45.8 ± 7.1 mg/dL (severe). The correlation coefficient ($r = 0.63$) was highly significant ($p < 0.001$).

Table 1: Demographics of the Study Participants

Characteristic	Mean ± SD / Count
Total Participants	100
Male	52
Female	48
Age (years)	56.3 ± 8.4
Age Range (years)	40 - 70

Table 2: Correlation between Fasting Plasma Glucose (FPG) and Disease Severity

Disease Severity	Mean FPG (mg/dL) ± SD	Correlation Coefficient (r)	p-value
Mild	139.4 ± 11.2	0.68	< 0.001
Moderate	167.3 ± 14.5	0.68	< 0.001
Severe	197.6 ± 17.6	0.68	< 0.001

Table 3: Correlation between Glycated Hemoglobin (HbA1c) and Disease Severity

Disease Severity	Mean HbA1c (%) ± SD	Correlation Coefficient (r)	p-value
Mild	7.1 ± 0.5	0.72	< 0.001
Moderate	8.2 ± 0.7	0.72	< 0.001
Severe	9.4 ± 0.8	0.72	< 0.001

Table 4: Correlation between C-Reactive Protein (CRP) and Disease Severity

Disease Severity	Mean CRP (mg/L) ± SD	Correlation Coefficient (r)	p-value
Mild	5.4 ± 1.2	0.54	< 0.01
Moderate	9.3 ± 1.6	0.54	< 0.01
Severe	12.8 ± 2.1	0.54	< 0.01

Table 5: Correlation between Lipid Profile and Disease Severity

Lipid Parameter	Disease Severity	Mean Value (mg/dL) ± SD	Correlation Coefficient (r)	p-value
Total Cholesterol	Mild	178.6 ± 14.3	0.42	< 0.05
	Moderate	201.4 ± 16.7	0.42	< 0.05
	Severe	220.4 ± 18.9	0.42	< 0.05
Triglycerides	Mild	150.3 ± 21.4	0.58	< 0.01
	Moderate	198.2 ± 23.6	0.58	< 0.01
	Severe	256.8 ± 26.1	0.58	< 0.01
HDL Cholesterol	Mild	46.2 ± 5.1	-0.37	< 0.05
	Moderate	39.7 ± 4.8	-0.37	< 0.05
	Severe	34.1 ± 4.2	-0.37	< 0.05

Table 6: Correlation between Serum Creatinine and Disease Severity

Disease Severity	Mean Serum Creatinine (mg/dL) ± SD	Correlation Coefficient (r)	p-value
Mild	0.9 ± 0.3	0.48	< 0.01
Moderate	1.2 ± 0.4	0.48	< 0.01
Severe	1.6 ± 0.5	0.48	< 0.01

Table 7: Correlation between Microalbuminuria and Disease Severity

Disease Severity	Mean Microalbuminuria (mg/dL) ± SD	Correlation Coefficient (r)	p-value
Mild	12.3 ± 3.4	0.63	< 0.001
Moderate	25.7 ± 5.8	0.63	< 0.001
Severe	45.8 ± 7.1	0.63	< 0.001

DISCUSSION

The present study aimed to explore the relationship between various serum biomarkers and disease severity in type 2 diabetes mellitus (T2DM). Our findings reinforce the importance of routinely monitoring key biomarkers such as fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), C-reactive protein (CRP), and lipid profiles to gauge disease progression.

Glycemic Markers and Disease Severity

Both FPG and HbA1c showed strong positive correlations with disease severity, suggesting that poor glycemic control accelerates disease progression[9]. This finding aligns with prior studies that established FPG and HbA1c as reliable markers for evaluating the metabolic status of T2DM patients. Their significant association with complications highlights the critical need for stringent glycemic control.[10]

Inflammation and Disease Severity

CRP, an inflammatory marker, was positively correlated with worsening disease severity. Chronic low-grade inflammation is a hallmark of T2DM, and elevated CRP levels may reflect systemic inflammation contributing to insulin resistance and diabetic complications. Thus, CRP could be a useful adjunct marker for assessing disease progression.[11,12]

Lipid Profile and Disease Severity

The lipid profile analysis revealed that triglycerides and total cholesterol levels were positively correlated with T2DM severity, while HDL cholesterol showed a negative correlation. Dyslipidemia is prevalent in T2DM due to insulin resistance, which impairs lipid metabolism, leading to elevated triglycerides and reduced HDL cholesterol. The lipid abnormalities observed underline the need for comprehensive cardiovascular risk management.[13]

Renal Markers and Disease Severity

Serum creatinine and microalbuminuria showed significant positive correlations with T2DM severity, suggesting a higher risk of nephropathy as the disease progresses. Monitoring these renal markers is essential to identify early signs of diabetic nephropathy, allowing for timely intervention to prevent kidney function deterioration.[14]

Study Limitations

Despite the comprehensive analysis, the study has limitations. First, the cross-sectional design provides

correlations but not causal relationships. Second, a larger and more diverse sample could help generalize the findings across different demographic groups.

CONCLUSION

This study demonstrates significant correlations between T2DM severity and key serum biomarkers. Higher levels of FPG, HbA1c, CRP, triglycerides, and serum creatinine, along with lower levels of HDL cholesterol, are associated with advanced disease. These findings highlight the critical role of routine biomarker monitoring in clinical practice to identify high-risk patients early and implement timely and effective intervention strategies.

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