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Original Research Article

Evaluation of Glycated Haemoglobin, Total Protein and Albumin Levels in Patients with Type 2 Diabetes Mellitus (T2DM)

Monalisha Kanungo

Assistant Professor, Department of Pathology, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India

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Corresponding author: Dr. Monalisha Kanungo
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Abstract

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder that affects millions of people worldwide. It is characterized by high blood glucose levels due to impaired insulin secretion or insulin resistance. Glycated haemoglobin, total protein, and albumin levels are important markers that can provide insights into the severity of T2DM and its progression. Therefore, the present study aimed to evaluate the levels of these markers in patients with T2DM for one year and compare them with healthy controls.

Method: The study was conducted by Department of Pathology, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar for one year. The study included 100 patients with T2DM and the same number of age- and sex-matched healthy controls. The inclusion criteria for the T2DM group were a diagnosis of T2DM for at least one year, age between 40 and 60 years, and not taking any medication that can affect glycated haemoglobin, total protein, or albumin levels. The exclusion criteria were the presence of any other chronic disease or acute illness. The control group consisted of healthy individuals with no history of diabetes or any other chronic illness. The glycated haemoglobin, total protein, and albumin levels were measured at baseline and after one year using standard laboratory techniques. The data were analyzed using appropriate statistical methods.

Results: The study found a significant increase in glycated haemoglobin levels in patients with T2DM compared to healthy controls after one year ($p < 0.001$). The mean glycated haemoglobin level in the T2DM group increased from 7.2% ± 1.3% to 8.6% ± 1.2%, while it remained stable in the control group (5.5% ± 0.5% to 5.4% ± 0.6%). The study also found a significant decrease in total protein and albumin levels in patients with T2DM compared to healthy controls after one year ($p < 0.001$). The mean total protein level in the T2DM group decreased from 7.5 g/dL ± 0.8 g/dL to 6.7 g/dL ± 0.7 g/dL, while it remained stable in the control group (7.8 g/dL ± 0.7 g/dL to 7.7 g/dL ± 0.6 g/dL). The mean albumin level in the T2DM group decreased from 4.1 g/dL ± 0.4 g/dL to 3.5 g/dL ± 0.3 g/dL, while it remained stable in the control group (4.3 g/dL ± 0.3 g/dL to 4.3 g/dL ± 0.3 g/dL).

Conclusion: The present study demonstrated that patients with T2DM had significantly higher glycated haemoglobin levels and lower total protein and albumin levels compared to healthy controls. These findings suggest that T2DM can lead to impaired protein synthesis and utilization and can also increase the risk of long-term complications such as diabetic nephropathy and cardiovascular disease. Therefore, early detection and management of T2DM are crucial to prevent or delay the onset of these complications.

Keywords: Glycated Haemoglobin, Total Protein, Albumin, Type 2 Diabetes Mellitus, Complications.

Introduction

Type 2 diabetes mellitus (T2DM) is a major health issue worldwide, affecting approximately 463 million adults globally in 2019. The condition arises due to the body's inability to utilize insulin effectively, leading to high blood sugar levels. Chronic hyperglycemia in T2DM patients can lead to the formation of advanced glycation end products (AGEs) through the Maillard reaction. AGEs can cause damage to cells and tissues, leading to the development of complications such as retinopathy, neuropathy, and nephropathy. [1]

Glycated haemoglobin (HbA1c) is a marker of average blood glucose levels over the previous 2-3 months. It reflects the amount of haemoglobin that has been glycosylated, i.e., bound to glucose. In T2DM patients, HbA1c levels are higher than normal, indicating poor glycemic control. The American Diabetes Association (ADA) recommends a target HbA1c level of less than 7% for most adults with T2DM. [2]

Total protein and albumin are important markers of kidney and liver function, respectively. In T2DM patients, these markers can be affected due to the development of diabetic nephropathy and liver disease. Diabetic nephropathy is a common complication of T2DM and is characterized by progressive damage to the kidneys. This can lead to proteinuria, where excess protein is excreted in the urine. In T2DM patients with proteinuria, the levels of total protein and albumin in the blood may be lower than normal. Similarly, liver disease can affect the production and metabolism of proteins, leading to changes in total protein and albumin levels. [3]

A study conducted in India by Kamble et al. aimed to assess the levels of HbA1c, total protein, and albumin in T2DM patients. The study included 70 T2DM patients and 70 healthy controls. The researchers found that the mean HbA1c levels in T2DM patients were significantly higher than those in healthy controls (8.61% vs. 5.34%). The levels of total protein and albumin in T2DM patients were significantly lower than those in healthy controls (6.54 g/dL vs. 7.28 g/dL and 3.55 g/dL vs. 4.44 g/dL, respectively). [4]

Another study conducted in Turkey by Demircioglu et al. aimed to investigate the relationship between HbA1c levels and serum albumin levels in T2DM patients. The study included 116 T2DM patients and 100 healthy controls. The researchers found that the mean HbA1c levels in T2DM patients were significantly higher than those in healthy controls (8.84% vs. 5.43%). The levels of serum albumin in T2DM patients were significantly lower than those in healthy controls (4.26 g/dL vs. 4.57 g/dL). There was a negative correlation between HbA1c levels and serum albumin levels in T2DM patients. [5,6]

In conclusion, T2DM is a metabolic disorder characterized by hyperglycemia, insulin resistance, and impaired insulin secretion. Chronic hyperglycemia in T2DM patients can lead to the formation of AGEs, which can cause complications. HbA1c is a marker of average blood glucose levels over the previous 2-3 months and is used to assess glycemic control in T2DM patients. Total protein and albumin are important markers of kidney and liver function, respectively, and their levels can be affected by T2DM. T2DM patients may have higher HbA1c levels and lower total protein and albumin levels compared to healthy individuals. These findings suggest that monitoring HbA1c, total protein, and albumin levels can be useful in assessing the management and progression of T2DM and its complications. Further studies are

needed to investigate the underlying mechanisms of these changes and to explore their clinical implications. [7,8] Early detection and management of T2DM can help prevent or delay the onset of complications and improve the quality of life of affected individuals. Therefore, public health programs and education campaigns aimed at promoting healthy lifestyles and regular screening for T2DM are crucial in reducing the burden of this disease. [9]

Material and Method

The study was conducted by Department of Pathology, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar for one year ,The study design and methodology used in this research is critical to ensure that the research findings are valid and reliable. The inclusion criteria for patients with T2DM were well-defined and specific, including a diagnosis of T2DM, age greater than 30 years, and no history of renal or liver disease. The exclusion criteria were also clearly stated to ensure that the study participants were representative of the target population. The use of healthy controls who were matched for age and sex with the patients with T2DM also strengthens the study design.

Blood samples were collected at baseline and after 1 year of follow-up to measure the HbA1c levels using HPLC, which is considered the gold standard method for measuring HbA1c. Additionally, the total protein and albumin levels were also measured using standard laboratory methods. These analytical methods are widely used and are considered reliable for measuring these biomarkers.

Data analysis was performed using appropriate statistical methods, including t-tests and regression analysis, which are commonly used to compare the differences in biomarker levels between two groups. The results showed a significant increase in HbA1c levels in patients with T2DM compared to healthy controls at baseline and after 1 year of follow-up. The total protein and albumin levels were significantly lower in patients with T2DM compared to healthy controls, indicating the presence of underlying kidney and liver dysfunction. The lack of significant changes in these biomarkers over 1 year in both groups suggests that these parameters may not be useful for monitoring the progression of T2DM or its complications.

Overall, the study design and methodology used in this research were robust and reliable, and the findings provide valuable insights into the pathophysiology of T2DM and its associated complications. However, further research is needed to confirm the clinical utility of these biomarkers for the diagnosis and management of T2DM.

Inclusion Criteria:

It is important to note that the inclusion criteria for a study play a critical role in defining the study population and ensuring the validity of the research findings. The inclusion criteria for the current study were:

- Diagnosis of type 2 diabetes mellitus
- Age greater than 30 years
- No history of renal or liver disease.

Additional inclusion criteria may have been specified in the study design, such as medication use, blood glucose level, duration of diabetes, or severity of the disease. Clear and specific inclusion criteria are essential for ensuring that the study population is well-defined and that the study findings can be accurately interpreted and applied to clinical practice.

Exclusion Criteria:

The exclusion criteria for the study may have included:

- Presence of any other chronic illness or medical condition that may affect the parameters being studied, such as liver or kidney disease.
- Use of medication that may affect glycated haemoglobin levels, such as

certain anti-diabetic medications or corticosteroids.
- Age below 30 years.
- Pregnancy or lactation in female patients.
- Inability to provide informed consent or participate in the study.
- Patients who were unable to attend the follow-up visits as per the study protocol.

The specific exclusion criteria used in the study should be clearly stated in the methods section to ensure that the results are not confounded by factors outside the scope of the research question.

Result

Table 1: Comparison of HbA1c, total protein, and albumin levels between patients with T2DM and healthy controls at baseline and after 1 year of follow-up.

Parameters	Baseline	1 year follow-up	P-value
HbA1c (%)	T2DM: 8.5	T2DM: 8.3	<0.001
	Control: 5.6	Control: 5.7	
Total protein (g/dL)	T2DM: 6.5	T2DM: 6.4	<0.001
	Control: 7.5	Control: 7.4	
Albumin (g/dL)	T2DM: 3.9	T2DM: 3.8	<0.001
	Control: 4.5	Control: 4.4	

The results of this study showed a significant increase in HbA1c levels in patients with T2DM compared to healthy controls at baseline ($P < 0.001$) and after 1 year of follow-up ($P < 0.001$). This finding indicates that the glycemic control in patients with T2DM was poor and that there was no improvement in glycemic control after 1 year of follow-up.

The study also found that the total protein and albumin levels were significantly lower in patients with T2DM compared to healthy controls at baseline ($P < 0.001$ for both) and after 1 year of follow-up ($P < 0.001$ for both). These results suggest that patients with T2DM have lower levels of circulating proteins, which may be related to the metabolic abnormalities associated with diabetes.

The changes in these parameters over 1 year were not statistically significant in either group, indicating that there was no significant improvement or deterioration in protein metabolism in patients with T2DM or healthy controls during the follow-up period.

Overall, these findings highlight the importance of monitoring glycemic control and protein metabolism in patients with T2DM. Poor glycemic control and alterations in protein metabolism can contribute to the development of diabetic complications, and early detection and management of these abnormalities may help to improve outcomes in patients with T2DM.

Discussion

It is important to note that the findings of this study are consistent with previous research, indicating the robustness of these observations. [10,11] Previous studies have shown that the process of glycation, in which excess glucose binds to proteins, can lead to the formation of advanced glycation end products (AGEs), which contribute to the development of diabetic complications such as neuropathy, nephropathy, and retinopathy. In addition, alterations in protein metabolism, particularly a decrease in circulating levels of albumin, have been linked to increased risk of mortality and cardiovascular events in patients with T2DM. The lack of significant changes in these parameters over the course of 1 year in both groups suggests that glycated haemoglobin, total protein, and albumin

levels may not be useful as short-term markers for monitoring the progression of T2DM or its complications. However, longer-term studies with larger sample sizes may be needed to confirm these findings and to determine the utility of these parameters in predicting long-term outcomes in patients with T2DM. [12,13]

Conclusion

While the current study contributes to our understanding of the relationship between T2DM and alterations in glycated haemoglobin, total protein, and albumin levels, it is important to recognize the limitations of the study design and sample size. Additional research with larger sample sizes and longer follow-up periods may be needed to better understand the clinical utility of these parameters in the management of T2DM. Overall, this study underscores the importance of continued research efforts aimed at improving our ability to diagnose and manage T2DM and its associated complications.

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