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ASSESSING THE RELATIONSHIP BETWEEN HBA1C AND URINARY ALBUMIN FOR EARLY NEPHROPATHY IN TYPE 2 DIABETES

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Abstract

Background: Urinary albumin excretion is considered an early marker of renal impairment in diabetic patients. The presence of albumin in urine, even in small amounts, signifies a disruption in the glomerular filtration barrier, which may precede overt clinical nephropathy. Several studies have indicated a correlation between HbA1c levels and urinary albumin excretion. Despite these findings, the relationship between HbA1c and urinary albumin excretion is complex and may be influenced by various factors, including the duration of diabetes, age, hypertension, and dyslipidemia. **Material & Methods:** A total of 180 subjects were included in the study diagnosed with Type 2 Diabetes Mellitus according to American Diabetes Association (ADA) criteria. **3** The cases were further categorized based on their albumin-to-creatinine ratio (ACR): 60 patients with normo-albuminuria (ACR < 30 mg/dL) and 60 patients with microalbuminuria (ACR 30-299 mg/dL). Additionally, 60 healthy subjects served as controls. The collected blood samples were centrifuged at 3000 rpm for 5 minutes, and the separated plasma was stored for biochemical analysis. The urine albumin-to-creatinine ratio was measured using the immune-turbidometric method. **Results:** A clear trend of worsening biochemical parameters with the progression from normo-albuminuria to micro-albuminuria, emphasizing the importance of early detection and management of blood sugar levels to prevent renal complications was seen. Observations also indicates a significant correlations between urine albumin levels and various biochemical parameters in Type 2 Diabetes Mellitus patients. The strongest correlation with serum creatinine underscores the importance of monitoring renal function in these patients, while associations with fasting and postprandial blood sugar levels, as well as HbA1C, highlight the role of glycemic control in the prevention of kidney complications. **Conclusion:** This study demonstrates a significant relationship between HbA1c levels and urinary albumin excretion in patients with type 2 diabetes, suggesting that higher HbA1c may indicate an increased risk of nephropathy. Regular monitoring of both markers is essential for early detection of renal complications, enabling timely interventions to preserve kidney function.

Keywords: Glycosylated hemoglobin, HbA1c, Urinary Albumin, Nephropathy, Type 2 Diabetes Mellitus

INTRODUCTION

Diabetes Mellitus has emerged as a global epidemic, with type 2 diabetes being the most prevalent form. According to the International Diabetes Federation, approximately 537 million adults worldwide were living with diabetes in 2021, a figure projected to rise to 643 million by 2030.[1] One of the most significant long-term complications of diabetes is diabetic nephropathy, which can lead to end-stage renal disease and significantly impact morbidity and mortality rates among diabetic patients.[2] Early identification of nephropathy is crucial for implementing preventive measures that can slow the progression of kidney disease.

Glycosylated hemoglobin (HbA1c) serves as a key biomarker for assessing glycemic control in diabetic patients. It reflects the average blood glucose levels over the preceding two to three months and is instrumental in diabetes management guidelines recommended by American Diabetes Association in 2022.[3] Elevated HbA1c levels are well-documented to correlate with microvascular complications, including retinopathy and neuropathy. However, its relationship with renal complications, particularly urinary albumin excretion remains a subject of ongoing research.

Urinary albumin excretion is considered an early marker of renal impairment in diabetic patients. The presence of albumin in urine, even in small amounts, signifies a disruption in the glomerular filtration barrier, which may precede overt clinical nephropathy.[4] The classification of urinary albumin levels into normoalbuminuria, microalbuminuria, and macroalbuminuria serves as a framework for identifying patients at risk for nephropathy. Microalbuminuria, defined as urinary albumin excretion between 30 and 300 mg per day, is particularly significant, as it is often reversible with improved glycemic control and management of other cardiovascular risk factors.[5]

Several studies have indicated a correlation between HbA1c levels and urinary albumin excretion. For instance, a longitudinal study done by Kahn et al. in 2016 [6] found that higher HbA1c levels were associated with an increased risk of developing microalbuminuria in patients with T2D. This association highlights the potential of HbA1c as a predictive marker for early nephropathy. Similarly, a meta-analysis conducted by Wu et al. in 2020 [7] demonstrated that individuals with elevated HbA1c had a significantly higher prevalence of microalbuminuria compared to those with well-controlled glycemia.

Despite these findings, the relationship between HbA1c and urinary albumin excretion is complex and may be influenced by various factors, including the duration of diabetes, age, hypertension, and dyslipidemia. Furthermore, some studies suggest that the link between glycemic control and renal outcomes may be moderated by the presence of other comorbidities or therapeutic interventions.[8] This complexity necessitates a more nuanced understanding of how HbA1c levels interact with urinary albumin as indicators of renal function.

The early detection of diabetic nephropathy through the assessment of HbA1c and urinary albumin levels could pave the way for timely interventions. The standard recommendation for patients with Type 2 Diabetes Mellitus includes annual screening for urinary albumin excretion, especially for those with suboptimal glycemic control by American Diabetes Association, 2022). [3] However, the integration of HbA1c monitoring could enhance the predictive power for nephropathy risk, enabling clinicians to stratify patients based on their likelihood of developing renal complications. Given the pressing need to mitigate the burden of diabetic nephropathy, the aim of this study is to assess the relationship between HbA1c and urinary albumin excretion in patients with Type 2 Diabetes Mellitus.

By analyzing this association, we seek to elucidate the extent to which glycemic control influences renal outcomes in the early stages of diabetes. Our hypothesis is that higher HbA1c levels will correlate with increased urinary albumin excretion, thereby serving as a valuable indicator for the early detection of nephropathy in individuals with Type 2 Diabetes Mellitus.

MATERIALS AND METHODS

Study Design and Setting:

A case-control study was conducted at a tertiary care hospital in Western Uttar Pradesh. A total of 180 subjects were included in the study diagnosed with Type 2 Diabetes Mellitus according to

American Diabetes Association (ADA) criteria. [3] The cases were further categorized based on their albumin-to-creatinine ratio (ACR): 60 patients with normo-albuminuria (ACR < 30 mg/dL) and 60 patients with microalbuminuria (ACR 30-299 mg/dL). Additionally, 60 healthy subjects served as controls.

Inclusion and Exclusion Criteria:
Participants included in the study were those aged over 30 years already diagnosed with Type 2 Diabetes Mellitus. However patients with a history of, hypercholesterolemia, cardiovascular disease, hepatic disorders, acute or chronic renal insufficiency, alcohol abuse, diagnosed or undergoing treatment of carcinoma , patients on chemotherapy or immunotherapy were excluded from the study.

Sample Collection:
After an overnight fasting of 12 hours, 5 mL of venous blood was collected from each subject. Of this, 2 mL was transferred into an anticoagulant tube containing fluoride, and 3 mL was placed in a plain tube for postprandial blood sugar (PPBS) analysis. Urine samples were also collected from all subjects.

Laboratory Analysis:
The collected blood samples were centrifuged at 3000 rpm for 5 minutes, and the separated plasma was stored for biochemical analysis. Parameters analyzed included fasting blood sugar, Post Prandial Blood Sugar, HbA1C, serum urea, creatinine, and uric acid, all assessed using standard laboratory methods. The urine albumin-to-creatinine ratio was measured using the immune-turbidometric method.

Statistical Analysis:
Data were compiled in Microsoft Excel spreadsheets and analyzed using SPSS software version 20. The significance of differences in Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), HbA1C, and urinary albumin levels was assessed using Analysis of Variance (ANOVA). Pearson correlation was employed to examine the relationships between HbA1C, urinary albumin, FBS, PPBS, urea, creatinine, and uric acid.. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1: Distribution of Demographic and Biochemical Parameters in different study groups

	Control group	Patients with Normo-albuminuria	Patients with Micro-albuminuria	p value
Age (years)	51.51±11.64	47.72±10.94	53.71±8.82	0.0766
Blood sugar (Fasting)	82.44±12.56	131.71±21.67	276.42±28.76	<0.005*
Blood sugar (Post prandial)	128.32±25.67	167.98±39.98	306.44±31.67	<0.005*
S. Urea	30.15±7.89	41.78±6.60	98.80±8.86	<0.005*
S. Creatinine	0.83±0.16	1.12±0.23	13.35±2.27	<0.005*
S. Uric Acid	6.11±1.98	7.18±1.10	13.67±0.72	<0.005*
HbA1C	4.16±1.87	7.68±1.89	12.55±6.34	<0.005*
Urine Albumin	14.55±0.76	28.15±1.10	202.78±31.65	<0.005*

Significant p value

- Blood Sugar, S. Urea, S. Creatinine, S. Uric Acid and Urine Albumin expressed in mg/dl
- HbA1C expressed in percentage (%)

Table 1 presents a comparative analysis of demographic and biochemical parameters among three groups: the control group, patients with normo-albuminuria, and patients with micro-albuminuria.

1. **Age**: The average age of participants in the control group was 51.51 years, while the normo-albuminuria and micro-albuminuria groups had averages of 47.72 years and 53.71 years, respectively. The p-value of 0.0766 indicates no statistically significant difference in age across the groups.
2. **Fasting Blood Sugar (FBS)**: There was a significant increase in FBS levels from the control group (82.44 mg/dL) to the normo-albuminuria (131.71 mg/dL) and micro-albuminuria groups (276.42 mg/dL), with a p-value of <0.005, suggesting a strong correlation between elevated FBS and the progression of kidney impairment.
3. **Postprandial Blood Sugar (PPBS)**: Similar to FBS, PPBS levels were significantly higher in both patient groups compared to controls (128.32 mg/dL in controls, 167.98 mg/dL in normo-albuminuria, and 306.44 mg/dL in micro-albuminuria), with a p-value of <0.005.
4. **Serum Urea**: The control group had a serum urea level of 30.15 mg/dL, which increased significantly to 41.78 mg/dL in the normo-albuminuria group and 98.80 mg/dL in the micro-albuminuria group ($p < 0.005$).
5. **Serum Creatinine**: There was a substantial rise in serum creatinine levels, from 0.83 mg/dL in the control group to 1.12 mg/dL in the normo-albuminuria group and a striking 13.35 mg/dL in the micro-albuminuria group, again showing significant differences ($p < 0.005$).
6. **Serum Uric Acid**: Uric acid levels also increased significantly across the groups, from 6.11 mg/dL in the control group to 7.18 mg/dL in the normo-albuminuria group and 13.67 mg/dL in the micro-albuminuria group ($p < 0.005$).
7. **HbA1C**: The control group's HbA1C level was 4.16%, whereas the levels in the normo-albuminuria and micro-albuminuria groups rose to 7.68% and 12.55%, respectively, indicating a significant correlation with kidney function status ($p < 0.005$).
8. **Urine Albumin**: Finally, urine albumin levels increased markedly from 14.55 mg/dL in the control group to 28.15 mg/dL in the normo-albuminuria group and 202.78 mg/dL in the micro-albuminuria group, with a p-value of <0.005 highlighting the significance of albuminuria in kidney dysfunction.

Overall, the data indicate a clear trend of worsening biochemical parameters with the progression from normo-albuminuria to micro-albuminuria, emphasizing the importance of early detection and management of blood sugar levels to prevent renal complications.

Table 2: Pearson Correlation between two groups of Type 2 Diabetes Mellitus patients

Pearson Correlation		r value	p value
Urine Albumin	**Age (years)**	0.028	0.755
	Blood sugar (Fasting)	0.189	<0.005*
	Blood sugar (Post prandial)	0.317	<0.005*
	S. Urea	0.178	<0.005*
	S. Creatinine	0.988	<0.005*
	S. Uric Acid	0.562	<0.005*
	HbA1C	0.524	<0.005*

Table 2 presents the Pearson correlation coefficients (r values) and associated p-values for various biochemical parameters in patients with Type 2 Diabetes Mellitus.

1. **Urine Albumin vs. Age**: The correlation between urine albumin and age is weak (r = 0.028) and not statistically significant (p = 0.755). This suggests that age does not have a meaningful impact on urine albumin levels in this cohort.
2. **Urine Albumin vs. Fasting Blood Sugar (FBS)**: A moderate positive correlation is observed (r = 0.189) with a statistically significant p-value (<0.005). This indicates that as fasting blood sugar levels increase, urine albumin levels tend to rise, reflecting potential kidney impairment associated with elevated glucose levels.
3. **Urine Albumin vs. Postprandial Blood Sugar (PPBS)**: There is a stronger positive correlation (r = 0.317) with a significant p-value (<0.005). This suggests that higher postprandial blood sugar levels are more strongly associated with increased urine albumin, indicating that postprandial hyperglycemia may contribute to renal dysfunction.
4. **Urine Albumin vs. Serum Urea**: A moderate correlation (r = 0.178) exists, with a statistically significant p-value (<0.005). This indicates that higher serum urea levels are associated with increased urine albumin, possibly reflecting worsening kidney function.
5. **Urine Albumin vs. Serum Creatinine**: The correlation here is exceptionally strong (r = 0.988) and statistically significant (p < 0.005). This indicates a near-perfect association, suggesting that increases in serum creatinine are almost directly proportional to increases in urine albumin, highlighting the critical relationship between renal function and albuminuria.
6. **Urine Albumin vs. Serum Uric Acid**: A moderate to strong positive correlation (r = 0.562) is observed, with a significant p-value (<0.005). This indicates that as serum uric acid levels increase, urine albumin levels also tend to rise, suggesting a potential link between hyperuricemia and kidney impairment.
7. **Urine Albumin vs. HbA1C**: A strong positive correlation (r = 0.524) with a statistically significant p-value (<0.005) indicates that higher HbA1C levels are associated with increased urine albumin, suggesting that poor long-term glycemic control contributes to renal damage.

The data indicate significant correlations between urine albumin levels and various biochemical parameters in Type 2 Diabetes Mellitus patients. The strongest correlation with serum creatinine underscores the importance of monitoring renal function in these patients, while associations with fasting and postprandial blood sugar levels, as well as HbA1C, highlight the role of glycemic control in the prevention of kidney complications.

DISCUSSION

The rising prevalence of type 2 diabetes poses a significant public health challenge, particularly due to its associated complications, including diabetic nephropathy. This study aimed to elucidate the relationship between HbA1c levels and urinary albumin excretion, as both serve as critical markers for assessing renal function and glycemic control. The findings indicate a robust correlation between elevated HbA1c and increased urinary albumin levels, underscoring the importance of regular monitoring of these parameters in managing patients with Type 2 Diabetes Mellitus.

Relationship Between HbA1c and Urinary Albumin

The positive association between HbA1c and urinary albumin in our study aligns with previous research that highlights the role of chronic hyperglycemia in the development of nephropathy. Chronic elevated blood glucose levels can lead to glomerular damage, resulting in increased permeability to albumin and subsequent albuminuria as seen in study done by Mora-Fernández et al. in 2014. [9]

Our results are consistent with findings from from study done by Kahn et al. in 2016 [10] which showed that higher HbA1c levels significantly correlated with the onset of microalbuminuria among Type 2 Diabetes Mellitus patients. These findings reinforce the concept that maintaining optimal glycemic control is crucial for protecting renal function.

Implications for Early Detection of Nephropathy

The early identification of diabetic nephropathy is critical for implementing timely interventions to prevent progression to end-stage renal disease. Current guidelines recommend annual screening for urinary albumin excretion, particularly in patients with suboptimal glycemic control according to American Diabetes Association, 2022). [3] Our study suggests that incorporating HbA1c monitoring can enhance the predictive capacity for early nephropathy, allowing healthcare providers to stratify patients according to their risk profiles. This dual approach could facilitate more personalized treatment strategies, focusing on aggressive glycemic control in patients presenting with elevated HbA1c and urinary albumin levels.

Role of Other Risk Factors

While our study primarily focused on the relationship between HbA1c and urinary albumin, it is essential to consider the influence of other risk factors such as hypertension, dyslipidemia, and duration of diabetes. Research indicates that hypertension is a significant risk factor for the development of diabetic nephropathy and can exacerbate renal impairment in patients with Type 2 Diabetes Mellitus as seen in study done by Eddy & Neilson in 2006). [11] Similarly, dyslipidemia, often accompanying T2D, has been linked to increased urinary albumin excretion and the progression of nephropathy as seen in study done by Mora-Fernandez et al. in 2014. [12] Future studies should explore these interactions to provide a more comprehensive understanding of the multifactorial nature of nephropathy in diabetes.

Therapeutic Interventions

The findings of this study have important implications for therapeutic interventions. The SGLT2 inhibitors and GLP-1 receptor agonists have emerged as pivotal agents in diabetes management, demonstrating benefits not only in glycemic control but also in renal outcomes similar to study done by Friedman et al. in 2020. [13] These medications have been shown to lower HbA1c and reduce urinary albumin excretion, thus addressing both components of nephropathy risk. Our results suggest that integrating HbA1c monitoring in routine clinical practice could guide the selection of appropriate pharmacological therapies aimed at reducing albuminuria and preserving renal function. Moreover, assessing additional biomarkers of kidney function, such as serum creatinine and estimated glomerular filtration rate (eGFR), could provide a more comprehensive evaluation of renal health in T2D patients. Investigating the potential role of novel biomarkers, such as urinary microRNAs and other inflammatory markers, may also enhance our understanding of the pathophysiology of diabetic nephropathy.

The study reinforces the significance of HbA1c as a reliable predictor of urinary albumin excretion in patients with type 2 diabetes. The strong association between elevated HbA1c and increased urinary albumin levels emphasizes the need for regular monitoring of both parameters in clinical practice. Timely interventions focused on glycemic control could significantly mitigate the risk of nephropathy, ultimately improving patient outcomes. As the prevalence of T2D continues to rise, a multifaceted approach incorporating both HbA1c and urinary albumin monitoring will be vital in addressing the burden of diabetic complications.

Recommendations

- **Longitudinal Studies**: Future research should employ a longitudinal design to better establish causality between HbA1c levels and urinary albumin excretion. This approach would allow for the examination of how changes in glycemic control over time influence renal outcomes.
- **Larger and Diverse Sample Sizes**: Conduct studies with larger and more diverse populations to enhance the generalizability of findings. Including various demographic groups (age, ethnicity, socioeconomic status) can provide a more comprehensive understanding of the relationship across different populations.

- **Inclusion of Additional Biomarkers**: Future research should incorporate other biomarkers of kidney function, such as serum creatinine and estimated glomerular filtration rate (eGFR). This will provide a more holistic view of renal health and the potential impact of glycemic control.
- **Multiple Measurements of Urinary Albumin**: Instead of relying on a single urinary albumin measurement, it is recommended to conduct multiple assessments over time. This would help capture fluctuations in albumin excretion and provide a clearer picture of chronic kidney changes.
- **Control for Confounding Factors**: Future studies should rigorously control for a broader range of potential confounding factors, including the duration of diabetes, comorbid conditions (such as hypertension and dyslipidemia), and specific treatment regimens. This will enhance the accuracy of findings and interpretations.
- **Standardization of Laboratory Methods**: Efforts should be made to standardize laboratory techniques for measuring HbA1c and urinary albumin to ensure consistency and reliability across studies. This would improve comparability and facilitate meta-analyses.

Limitations

- **Cross-Sectional Design**: The cross-sectional nature of the study limits the ability to establish causality between HbA1c levels and urinary albumin excretion. While a correlation can be identified, it is difficult to determine whether elevated HbA1c directly contributes to increased urinary albumin or if other factors mediate this relationship.
- **Sample Size and Population Diversity**: The sample size may not adequately represent the broader population of individuals with type 2 diabetes. A limited demographic diversity could affect the generalizability of the findings. Future studies should aim for larger, more diverse populations to better understand variations across different ethnicities and age groups.
- **Potential Confounding Factors**: While the study controlled for several variables, it may not have accounted for all potential confounders such as the duration of diabetes, specific medication regimens, dietary habits, and lifestyle factors (e.g., physical activity, smoking). These factors can significantly influence both glycemic control and renal function.
- **Single Measurement of Urinary Albumin**: The assessment of urinary albumin was based on a single measurement rather than multiple assessments over time. This approach may not accurately reflect chronic conditions such as microalbuminuria, which can fluctuate due to various factors, including infections or acute illness.
- **Exclusion of Other Biomarkers**: The study focused solely on HbA1c and urinary albumin, potentially overlooking other important biomarkers of kidney function, such as serum creatinine levels and estimated glomerular filtration rate (eGFR). Incorporating these measures could provide a more comprehensive assessment of renal health.
- **Influence of Comorbidities**: Patients with type 2 diabetes often have comorbid conditions such as hypertension and dyslipidemia, which can complicate the interpretation of results. The impact of these comorbidities on kidney function and glycemic control should be considered in future analyses.

CONCLUSION

This study demonstrates a significant relationship between HbA1c levels and urinary albumin excretion in patients with type 2 diabetes, suggesting that higher HbA1c may indicate an increased risk of nephropathy. Regular monitoring of both markers is essential for early detection of renal complications, enabling timely interventions to preserve kidney function. These findings underscore the need for integrating HbA1c and urinary albumin assessments into routine diabetes care. Future research should further explore this relationship across diverse populations to enhance understanding and management of diabetic nephropathy, ultimately improving patient outcomes.

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