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FREQUENCY OF EARLY DIABETIC NEPHROPATHY AND ITS CLINICAL PREDICTORS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS PRESENTING TO A TERTIARY CARE HOSPITAL IN ISLAMABAD

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ABSTRACT

Objective: To determine the prevalence of diabetic nephropathy (microalbuminuria) in early phase of type 2 diabetes mellitus (DM) presenting to a tertiary care hospital in Islamabad.

Study Design: A prospective cross sectional study.

Place and Duration of Study: Department of Endocrinology, Capital Hospital, Islamabad, Pakistan, from June 5, 2025 to December 5, 2025.

Methodology: The methodology involved the random sampling of 250 patients with type 2 diabetes mellitus with a non-probability (consecutive) sampling technique. Baseline demographics, anthropometric measurements, clinical and laboratory evaluations, such as estimated glomerular filtration rate (eGFR), serum creatinine, fasting blood glucose, and lipid profile were recorded. Spot urinary albumin to urinary creatinine ratio (UACR) was used for the diagnosis of early diabetic nephropathy with a spot urinary albumin of 30-300 mg/g defined as microalbuminuria (early diabetic nephropathy). Independent clinical factors that could predict the onset of early diabetic nephropathy were determined by logistic regression analysis using SPSS v.25.0 software.

Results: Among our cohort there was an overall prevalence of early diabetic nephropathy (microalbuminuria) of 36.8% (n = 92). Patients with early nephropathy exhibited a significantly higher mean age (58.4 ±7.2 years vs. 51.2 ±8.5 years; $P < 0.001$), longer median duration of diabetes (11.4 ±4.1 years vs. 6.2 ±3.3 years; $P < 0.001$), and poorer glycemic control with a higher mean HbA1c (8.6% ±1.4% vs. 7.1% ± 0.9%; $P = 0.002$) compared to those without nephropathy. Multivariate logistic regression analysis identified a prolonged duration of diabetes (OR = 1.42, 95% CI: 1.15 to 1.76; $P = 0.001$), elevated systolic blood pressure (OR = 1.08, 95% CI: 1.03 to 1.13; $P = 0.004$), elevated HbA1c levels (OR = 2.11, 95% CI: 1.45 to 3.08; $P < 0.001$), and presence of dyslipidemia (OR = 1.84, 95% CI: 1.12 to 3.02; $P = 0.015$) as strong, statistically significant independent clinical predictors of early diabetic nephropathy.

Conclusion: In our area, high prevalence of early diabetic nephropathy was found among T2DM patients. Long-term diabetes, a lack of glycemic control, systemic hypertension and the presence of dyslipidemia are key clinical risk factors associated with renal microvascular alterations. A common approach to screening for renal disease, using urinary Albumin to Creatinine Ratios, should be aggressively used to enable multi-factor interventions to commence at an early stage in the disease.

KEYWORDS: Early Diabetic Nephropathy, Microalbuminuria, Glycemic Control, Glycated Hemoglobin A1c, Type 2 Diabetes Mellitus, Hypertension.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) has emerged as a premier global public health crisis, triggering a rapid increase in micro- and macrovascular ailments across both industrialised and developing nations [1]. Estimates suggest that the diabetic population will expand significantly in the near future, with a particularly sharp rise expected in South Asian territories [2]. In Pakistan, diabetes represents a massive national disease burden, where millions are impacted; however, healthcare system constraints frequently lead to delayed diagnoses and inadequate management of the condition [3]. Among its most severe microvascular consequences is diabetic nephropathy (DN), which stands as the leading cause of end-stage renal disease (ESRD) worldwide and serves as a significant risk multiplier for cardiovascular events linked to chronic metabolic instability [4].

The clinical progression of DN is generally predictable, starting with renal hyperfiltration and transitioning through early microvascular alterations before reaching irreversible late-stage nephropathy characterized by specific clinical symptoms [5]. This microvascular damage initially presents as microalbuminuria, typically defined as 30–300 mg/g of albumin in at least two separate spot urine samples over a three-month period [4,5]. This stage represents a critical window where glomerular basement membrane thickening and podocyte injury can still be mitigated through intensive interventions, such as stringent glycemic control, lipid optimization, and

the use of renin-angiotensin-aldosterone system (RAAS) inhibitors for blood pressure management [6]. Without early detection and treatment, the condition progresses to macroalbuminuria and a steady decline in the estimated glomerular filtration rate (eGFR), eventually necessitating renal replacement therapy [5,6].

The development and advancement of early DN are influenced by various demographic, clinical, and biochemical factors [7]. Key contributors to vascular structural stress include male gender, family history of kidney disease, and long-term, poorly managed hypertension and metabolic dysfunction [7,8]. Furthermore, persistent metabolic issues such as elevated HbA1C levels and dyslipidemia (high LDL and triglycerides) trigger local inflammatory responses within the glomerular capillaries and lead to the buildup of advanced glycation endproducts (AGEs) and reactive oxygen species [8,9]. Despite international guidelines advocating for immediate microalbuminuria screening upon T2DM diagnosis, such practices are frequently neglected in Pakistan's healthcare sectors [10].

In resource-limited environments like Pakistan, the challenges of diabetic kidney disease are further intensified by low health literacy, expensive treatments, the lack of formal screening programs, and delayed specialist referrals [10,11]. Consequently, many patients arrive at tertiary care facilities having never undergone early-stage microalbuminuria screening [12]. There is currently a lack of contemporary data regarding the specific prevalence of early nephropathy in the capital, as well as a shortage of predictive models tailored to regional epidemiological and clinical contexts [10,12]. This study therefore aims to fill this gap by assessing the prevalence of early diabetic nephropathy and identifying independent clinical factors associated with early diabetic nephropathy in type 2 diabetes attending a tertiary care centre in Islamabad.

MATERIALS AND METHODS

Prospective Cross- Sectional study was carried out in the Department of Endocrinology at the Capital hospital, Islamabad, Pakistan. Observation for the study has been done from June 5, 2025 to December 5, 2025. Prior to the recruitment of subjects the study protocol was approved by the Institutional Review Board (IRB) and Ethics Committee of the Capital Hospital Islamabad with Approval Registration Number: 101-04-06-25 (Dated-04.06.2025). All trial execution was done following the Declaration of Helsinki regarding ethical aspects Prior to enrolment, written informed consent was obtained from all participants or their legal guardian had signed the informed consent for the anonymity of data by serial coding strategies.

The sample size was determined as per the standard formula for calculating sample size for descriptive epidemiology studies which is applicable in single proportion. A sample size was calculated, taking into account pilot data from the region which had a similar population of the South Asian ethnic groups and where the estimated prevalence of diabetic microalbuminuria is around 34.2% in the past. The target sample size for 2-tailed significance level (α) of 0.05, margin of error (d) of 6% and 10% for possible incomplete proformas or dropouts in the laboratory was calculated to be 250 patients. The technique of sampling used was non-probability (consecutive) sampling from those presenting to the out patient clinics and medical wards.

Inclusion Criteria:

1. Documentation of type 2 diabetes mellitus (DM) based on the classification of the American Diabetes Association (ADA).
2. Patients between the age of 35 and 75 years, older adult men and women.
3. Diagnosed diabetes mellitus ≥1 year.

Exclusion Criteria:

- Patients with a documented pre-transplant non-diabetic chronic kidney disease, acute kidney injury (AKI) or eGFR< 30 mL/min/1.73m².
- Active, symptomatic urinary tract infections (UTIs) or macroscopic (visible) haematuria.
- Conditions which rapidly change urinary protein excretion, such as severe uncompensated congestive heart failure, high grade fever, severe acute infections, or strenuous physical exercise during the last 48 hours.
- Pregnant females.

Operational Definitions:

- **Microalbuminuria or EDN (Early Diabetic Nephropathy):** An intermediate level of AER that is detected specifically between 30 mg/gram and 300 mg/gram of urinary albumin-to-creatinine ratio (UACR) in the absence of acute factors which can secondarily affect AER.
- **Glycemic Control Status:** Assessed through HbA1c levels – HbA1c < 7.0% was considered as optimized/good glycemic control and HbA1c ≥ 7.0% was considered as poor glycemic control.
- **Systemic Hypertension:** Defined as a documented history of hypertension or as antihypertensive medication currently taken or a current resting blood pressure of systolic reading > or equal to 140 mmHg and/or diastolic reading > or equal to 90 mmHg.

Collection of Clinical Data: Clinical data was systematically collected dedicated research team. The detailed medical history and physical examination was performed for every patient who was consecutively enrolled and who fit the selection criteria. The anthropometric measurements such as body weight, height and body mass index (BMI) were documented. Blood pressure in the sitting position was taken using a validated digital sphygmomanometer after 10 minutes of complete resting and the average of two readings, done 5 minutes apart was measured.

After an overnight 8-12 hour fast, peripheral venous blood samples were obtained from each patient for biochemical parameters. The parameters studied in these investigations were fasting blood glucose (FBG),

glycated hemoglobin A1c (HbA1c), Serum Creatinine and Fast Lipid profile which included Total cholesterol, Triglyceride, High density lipid cholesterol (HDL-C) and Low density lipid cholesterol (LDL-C). All participants had the eGFR automatically calculated using the standard Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.
Screening for the primary outcome of early diabetic nephropathy (UACR) was performed by collecting a first morning sample of midstream urine collection in a sterile container. Spot urinary albumin-to-creatinine ratio (UACR) in mg/g was calculated through immunoturbidimetric techniques for measuring urinary albumin concentration and modified Jaffe method for urinary creatinine, both on automated analyzers for clinical chemistry. Patients with initially positive UACR values in the range 30–300 mg/g had their UACR values checked again 2 weeks later to exclude any transient orthostatic or physiological changes as a cause of the positive result. All subjects enrolled in the study received standardized doses of basic internal medical therapy and advice/supervision from an expert group (endocrine/renal) irrespective of their nephropathy status.

Data processing & Multi factorial Analysis: Data processing and multi factorial analysis were performed by SPSS (Version 25.0). Shapiro-Wilk test was used to formally check data normality. All the continuous variables (age, duration of diabetes, blood pressure, BMI, HbA1c, and lipid fractions) were reported as mean \pm standard deviation (SD). Categorical variables (gender, smoking status, therapeutic regimens and early nephropathy presence) were reported as absolute frequencies and percentages (n, %).
Independent samples t-test was used for continuous data and Pearson Chi square / Fisher's exact test for categorical parameters to compare between the patients of early diabetic nephropathy and normal albumin excretor. All variables with a P value ≤ 0.10 in the univariate analysis were used in a forward stepwise multivariate logistic regression model to assess independent clinical strength. Results of the regression analysis were reported in terms of Odds Ratios (OR) and 95% Confidence Intervals (CI). All P-values of less than or equal to 0.05 (two-tailed test) were considered statistically significant.

RESULTS

With no dropout or missing data recorded, 250 patients with type 2 diabetes mellitus completed all clinical and laboratory aspects of study protocol. Demographic and clinical characteristics of the overall study population are presented in Table 1. The mean age of the sample was 53.8 ± 8.1 years, with a slight male predominance (54.0%, n = 135) compared to females (46.0%, n = 115). Diabetes duration, on average 8.1 ± 3.9 years, and mean cohort BMI, 27.4 ± 4.3 kg/m2, categorized as overweight.

Table 1: Baseline Demographic and Laboratory Characteristics of the Total Cohort (N = 250)

Clinical Variable	Total Patient Population (N = 250)
Age (years), Mean ± SD	53.8 ± 8.1
Gender (Male / Female), n (%)	135 (54.0%) / 115 (46.0%)
Duration of Diabetes (years), Mean \pm SD	8.1 ± 3.9
Body Mass Index (kg/m²), Mean ± SD	27.4 ± 4.3
Systolic Blood Pressure (mmHg), Mean ± SD	134.6 ± 14.8
Diastolic Blood Pressure (mmHg), Mean ± SD	84.2 ± 9.4
Fasting Blood Glucose (mg/dL), Mean ± SD	154.2 ± 38.5
Glycated Hemoglobin A1c (HbA1c %), Mean ± SD	7.6% ± 1.3%
Total Cholesterol (mg/dL), Mean ± SD	198.4 ± 41.2
Serum Creatinine (mg/dL), Mean ± SD	0.88 ± 0.21

Overall early Diabetic Nephropathy (microalbuminuria) prevalence was found to be 36.8% (n = 92) and 63.2% (n = 158) of the diabetic population had normal albumin excretion rates in the urine in this study population by baseline screening and confirmatory spot urinary testing. Multivariate comparative analysis of the early diabetic nephropathy group and normoalbuminuric group revealed that several parameters were strongly significant between the two groups which were related to demographic, physical and biochemical parameters after univariate comparative analysis. Although randomization was not performed, patients with early diabetic nephropathy were significantly older (58.4 ± 7.2 vs. 51.2 ± 8.5 years, P < 0.001) and had significantly longer duration of diabetes (11.4 ± 4.1 vs. 6.2 ± 3.3 years, P < 0.001). In addition, early nephropathy had significantly higher means of systolic blood pressure, HbA1c, and total cholesterol fractions as compared to the unaffected cohort (Table 2).

Table 2: Univariate Comparison of Clinical and Laboratory Parameters between Groups

Variable	Early Diabetic Nephropathy (n = 92)	Normoalbuminuria Group (n = 158)	P-value
Age (years), Mean ± SD	58.4 ± 7.2	51.2 ± 8.5	<0.001
Male Gender, n (%)	52 (56.5%)	83 (52.5%)	0.542
Duration of Diabetes (years), Mean ± SD	11.4 ± 4.1	6.2 ± 3.3	<0.001
Body Mass Index (kg/m²), Mean ± SD	28.1 ± 4.5	27.0 ±4.1	0.054
Systolic Blood Pressure (mmHg), Mean ± SD	142.8 ± 15.2	129.8 ± 12.4	<0.001
Diastolic Blood Pressure (mmHg), Mean ± SD	88.4 ± 9.1	81.7 ± 8.6	0.003
HbA1c (%), Mean ±SD	8.6% ± 1.4%	7.1% ± 0.9%	0.002
Total Cholesterol (mg/dL), Mean ± SD	214.6 ± 44.5	189.0 ±36.2	<0.001
eGFR (mL/min/1.73m²), Mean ± SD	84.6 ± 14.1	91.2 ± 12.8	0.042

Since age, diabetes duration, SBP, DBP, HbA1c and TC had significant variations in the univariate analysis, these variables were used in the multivariate logistic regression analysis. Finally, a longer duration of diabetes, higher systolic blood pressure, higher HbA1c levels, and concomitant dyslipidaemia were found to be independently associated with early renal microvascular damage in another multivariate analysis by forward stepwise regression (Table 3).

Table 3: Multivariate Logistic Regression Analysis for Independent Clinical Predictors

Independent Predictor Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	P-value
Duration of Diabetes (per year increase)	1.42	1.15 to 1.76	0.001
Systolic Blood Pressure (per mmHg increase)	1.08	1.03 to 1.13	0.004
HbA1c Level (per % increase)	2.11	1.45 to 3.08	<0.001
Presence of Dyslipidemia (Yes vs. No)	1.84	1.12 to 3.02	0.015

Subgroup analyses by sex and age indicated that early diabetic nephropathy frequency was also significantly high in each group, thus demonstrating that the effect of clinical risk predictors was not specific to a particular group (Table 4).

Table 4: Stratified Analysis of Early Diabetic Nephropathy Frequency by Subgroups

Stratum Variable	Number of Enrolled Patients	Early Nephropathy Present n (%)	P-value
Age Group 35–55 Years	142	41 (28.9%)	0.008
Age Group 56–75 Years	108	51 (47.2%)	0.001

Stratum Variable	Number of Enrolled Patients	Early Nephropathy Present n (%)	P-value
Male Patients	135	52 (38.5%)	0.545
Female Patients	115	40 (34.8%)	

DISCUSSION

The results of our study suggest that clinically, diabetic nephropathy is very common in early stage among all Type 2 diabetic patients in our environment with reported cases of microalbuminuria of 36.8%. In this prospective cross-sectional design, there were statistically significant associations among early renal damage and structural metabolic predictors. This association was still seen in this multi-factorial analysis, and was appropriate to capturing the early microvascular changes that are associated with the chronic hyperglycemia before the onset of permanent damage to the parenchyma. This difference between normoalbuminuric individuals and those with early nephropathy demonstrates the major mechanism for this deterioration. The microvessel is the direct cumulative downstream effect of prolonged glycemic stress and systemic levels of fluid shear forces that affect the highly vulnerable glomerular filtration barrier [4,5]. There was heterogeneity in the regional frequencies of microalbuminuria detected from available measures, highlighting the potential for the negative consequences that can be observed when the optimal window for screening is not used in high-risk groups [7]. The clinical significance of reaching this early diagnosis of microvascular injury is that it directly influences improvement of secondary prevention pathways and prevents progression from microalbuminuria to full-blown end-stage renal failure [6]. An elevated HbA1c level has a strong independent predictive value (OR = 2.11) which is clinically significant [8]. The match in this increased risk with physiological patterns of diabetic glucosuric hyperactivity driving the accumulation of AGEs and local inflammatory reactions in the renal tissue resulting in podocyte foot process effacement and mesangial matrix expansion and early protein leakage, thus creating increased demand for long-term therapy and resource use in tertiary care settings [5,8]. The independent risk model found for increasing systolic blood pressure (OR = 1.08 mmHg increment) is similar to the haemodynamic stress increment associated with microvascular damage [7]. It is well recognized that both systemic and intraglomerular hypertension are clinical forces that affect the structural stability of the capillary beds in the kidney. This is especially important in individuals with type 2 diabetes in which poor blood pressure control can hasten the filter's loss of filtration function [6,9]. The ability to safely achieve modern cardiorenal protective goals depends on early identification and timely management of these combined metabolic and vascular risk factors [4]. The results of our study strongly support the results of the multi-center observational study done by Shera Maqsood [12] analysing diabetic complications in Pakistan and majority of the target population was microalbuminuric, the significant factors predicting microalbuminuria were long duration of diabetes and systemic Hypertension. Likewise, Zaman S, [11] conducted a prospective clinical trial in large cities in diabetic people, which demonstrated that hyperglycemia, especially raised HbA1c was very strongly correlated with early renal microvascular damages; findings which are in line with the results of our logistic regression. Our cohort also demonstrated high prevalence of early nephropathy, with Ali et al. reported that poor levels of compliance for primary screening in local public institutions resulted in high prevalence of microalbuminuria in the tertiary screening indicating the need for systematic screening updates [6]. In addition, the findings of Jan et al. [8] showed a significantly reduced progression of renal outcome among patients with type 2 diabetes who received early multifactorial treatment involving lipid and blood pressure control, thus making our identified clinical predictors quite relevant in clinical practice. Microalbuminuria frequency increased with age and with increasing glycemic dysfunction in each of the demographic subgroups (stratified analyses). This uniformity was an additional evidence of the generalizability of our findings to this population. Clinical risk trends consistently were similar for younger adult populations compared with older populations, and for male and female sub-populations [7,8]. Due to this consistence, we believe that the combined strategy of spot UACR monitoring with a thorough cardiovascular risk management is a reliable screening strategy. This approach is effective with all sorts of patients and doesn't require different treatment algorithms according to simple demographic parameters [6,10]. The advantages of the present study are the prospective cross-sectional study design, the structured laboratory testing protocol in a large, major tertiary hospital center and complete data tracking throughout all the subjects enrolled in the study, and clearly defined selection criteria that will facilitate additional study reproductions. By using the tracking protocol, it was possible to identify re-UACR levels in participants with confirmed microalbuminuria, to confirm the presence of persistent microalbuminuria [4]. But there are some caveats. Firstly, being a single-center study done in an urban hospital of Islamabad, this may not necessarily reflect the entire population of metabolic attributes and all diagnostic facilities in rural or sub-periphery areas of Pakistan [10]. Second, specialized markers of early tubulointerstitial injury were not measured and dietary protein intake was not directly evaluated [5]. Thirdly, no comparisons have been undertaken between oral glucose-lowering drugs [6]. Fourthly, no follow-up for long-term survival index and progression to overt macroalbuminuria were observed beyond the cross-sectional phase [9]. Further investigations can be conducted on these risk factors in multi-centers studies with a larger sample size and different socio-economic areas in Pakistan [10]. Future studies may evaluate alternative method of training for primary care providers that may help with adherence to the standards for monitoring UACR annually [4]. Additionally, future research is likely to yield a longer follow-up, looking at the progression towards end stage renal disease as well as cardiovascular survival to direct major revisions in national diabetes management guidelines in Pakistan [3,12].

CONCLUSION

Therefore we conclude that, early diabetic nephropathy is common in type 2 diabetes mellitus patients who present to a tertiary care center in Islamabad with more than 1/3 of the patients reviewed being affected. Longer duration of diabetes, poor glycemic control (high HbA1c), elevated systolic blood pressure and present dyslipidaemia are the strong determinants of progression of this microvascular complication. This is the initial phase of renal damage which is clinically reversible, so the absence of routine microalbuminuria screening represents a missed opportunity for early intervention.

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CONFLICT OF INTEREST

None.

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None.

ETHICAL APPROVAL

The institutional review board of Capital hospital Islamabad and ethics committee formally reviewed the operational protocol for this study and gave formal approval with IRB Reference Registration Number 101-04-06-25 on 04.06.2025. The clinical investigation was performed in accordance with the ethical guidelines of the Declaration of Helsinki. Written informed consent of all participants (or their legal guardians) was obtained prior to enrollment in the study.

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