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Original Article

Frequency of Diabetic Nephropathy among Patients of Type 2 Diabetes Mellitus

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ABSTRACT

Objective: To determine the frequency and prevalence of diabetic nephropathy in patients of Type 2 diabetes mellitus.
Study Design: Cross Sectional Study.
Place and Duration of Study: Department of Medicine, Combined Military Hospital, Bahawalpur Pakistan, from Jul to Nov 2021.
Methodology: One hundred and sixty patients of type 2 diabetes were included and comprehensive initial assessment, including detailed history, demographic data, and detection of microvascular complications through fundoscopy and neurological examinations, was done. All patients were checked for albuminuria for diagnosis of diabetic nephropathy and frequency of diabetic nephropathy was studied.
Results: There were 82(51.3%) males and 78(48.7%) females. Microalbuminuria was found in 20(12.5%) patients and macroalbuminuria in 62(38.8%). The mean serum creatinine level and eGFR was 1.156±0.53 mg/dl and 68.12±24.39% respectively. The mean HbA1c and Fasting Blood Sugar (FBS) levels were 8.38±1.84% and 136.86±19.25mg/dl respectively. Diabetic nephropathy was most commonly seen in 50-59 years age group i.e. 34(21.2%) patients. Fifteen (9.37%) patients with FBS ≤140 mg/dl and 44(27.5%) with FBS more than 140 md/dl had diabetic nephropathy (p<0.001). Twenty-one (13.1%) patients had eGFR 45-59%, 32(20.0%) had eGFR 30-44% and 6(3.7%) patients with diabetic nephropathy had eGFR 15-29% (p<0.001). Diabetic nephropathy in patients with HbA1c level ≤7.5% and >7.5% was seen in 12(7.5%) vs 47(29.3%) respectively (p=0.006).
Conclusion: There was significantly higher risk of Diabetic Nephropathy among patients having poor glycemic control, a long diabetes history, systolic hypertension, and a high Body Mass Index.

Keywords: Chronic Kidney Disease, Diabetes Mellitus, Diabetic Nephropathy, Hypertension, Microalbuminuria, Neuropathy, Retinopathy.

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INTRODUCTION

Diabetes mellitus (DM) is becoming a challenge for healthcare systems and affecting the quality of life. The number of persons with diabetes is on the exponential rise and currently stands at over 422 million, as reported by World Health Organization.[1] More than ninety percent of individual with diabetes have type 2 diabetes mellitus (T2DM). Diabetic nephropathy (DN) is the leading cause of morbidity and mortality among different microvascular complications of DM. It is thought to be one of the main causes of end-stage renal disease (ESRD) and cardiovascular diseases. T2DM patients are more prone to develop DN (40%) compared to Type I Diabetes Mellitus (T1DM) (30%).[2]

Diabetic nephropathy (DN) is characterized by an increase in albumin excretion, a decrease in GFR, or both. It impairs kidney function and changes the normal process of eliminating waste and extra fluid from the body, leading to chronic kidney disease (CKD).[3,4]

Data from China, shows the prevalence of CKD in 15856 diabetic patients as 38.8%.[5] One Asian study reported a composite prevalence of diabetic kidney disease of 62.3%.[6] A prospective study from England that included 4006 T2DM patients found that 28% developed renal impairment over a 15-year follow-up period. In the United States, the prevalence of diabetic nephropathy was 2.2%.[7] Diabetic kidney disease increase the mortality risk by 31.1%.[8]

In developed countries, the prevalence and risk factors of diabetic nephropathy are extensively established. In Pakistan, however, there is a lack of studies pertaining to diabetic nephropathy and its predictors. It is essential to examine the prevalence and risk factors related with diabetic nephropathy in T2DM patients to estimate the disease's burden and limiting predisposing factors, which is why we chose to conduct the current study.

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METHODOLOGY

This cross-sectional study was carried out at the Combined Military Hospital, Bahawalpur Pakistan, following approval from Hospital Ethical Committee (EC-10-2022) over a period of 6 months from July 2021 to November 2021.

Inclusion Criteria: Adult patients of either gender diagnosed patients of Type 2 Diabetes Mellitus (T2DM) were included.

Exclusion Criteria: Patients who had T1DM, obstructive uropathy, congestive heart failure, liver diseases, autoimmune diseases, neoplasm, UTI, taking medications that could affect insulin sensitivity such as steroids and hormone replacement therapy were excluded, as were those. taking medication that affect kidney function or who had an acute kidney injury in the last 6 months.

A sample size of 160 patients was calculated by estimating prevalence of diabetic nephropathy of 11.77% using OpenEpi Calculator.[9]

A semi structured questionnaire was used to collect data from the patients. On initial screening, detailed history and examination regarding age, height, weight, duration of disease, treatment taking for diabetes, associated co-morbidities. All the patients were examined for other microvascular complication of diabetes e.g., diabetic retinopathy and neuropathy with fundoscopy and nervous system examination respectively. The systolic and diastolic blood pressure was measured on two different occasions. Systolic blood pressure (BP) of >140 mmHg and diastolic BP of >90 mmHg. Normal BP measurements taken by taking 2 readings 3-4 min apart in sitting position.

The patients were given sterile plastic containers and were advised to collect mid-stream urine into the containers for the albumin/creatinine ratio test. Immediately, urine samples were stored at 2-4 °C. To stop bacterial overgrowth, sodium azide (0.02%) was added to the urine sample. All samples before the assay were mixed well. An immunoturbidimetric test called Randox Microalbumin was used to determine how much microalbumin there was. In the laboratory, a spectrophotometer was used to calculate results. Jeffe's reaction was used to determine the urinary creatinine concentration of a urine sample. Positive urine samples for leucocytes and nitrites, which indicate UTI, and RBC of 5 counts/L, which indicate a significant hematuria (false positives), were discarded. In the hospital's central laboratory, a blood sample was examined for fasting blood sugar, glycosylated haemoglobin (HbA1c), and serum creatinine. We checked the kidney function twice, at least three months apart, by measuring the amount of albumin in the urine and the amount of creatinine in the blood. Normal albumin excretion was defined as <30 mcg/mg of creatinine; microalbuminuria is 30–299 mcg/mg of creatinine, and macroalbuminuria is >300 mcg/mg of creatinine in two of the three tests within three months. Diabetic nephropathy was defined as a reduction in eGFR <60 mL/min/1.73 m2, persistent albuminuria (>300 mg/d) confirmed on at least two occasions 3-6 months apart, provided that other causes of CKD are ruled out.[10]

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0. Categorical variables were presented as frequency and percentages and quantitative variables were presented as mean and standard deviation. Fisher exact test was applied to check for association between variables and independent sample t-test to compare means. A *p*-value less than 0.05 was regarded as statistically significant.

RESULTS

Among 160 patients with Type II Diabetes Mellitus (T2DM), there were 82(51.3%) males and 78(48.7%) females with almost similar male to female ratio. The mean age of the patient was 56.28±9.90 years. Most of the patients 68(42.5%) were in 50-59 years age group. Thirty-six patients (22.5%) had a BMI between 18-24 kg/m2, fifty-three (33.1%) had a BMI between 25-30 kg/m2, forty-eight (30.0%) had a BMI between 31-35 kg/m2 and twenty-three (14.4%) had a BMI ≥36 kg/m2.

According to operational definition of albuminuria, 78(48.8%) patients had normal albuminuria, 20(12.5%) patients had microalbuminuria and remaining 62(38.8%) had macroalbuminuria. Among 160 patients, 52(32.5%) patients had stage 1 chronic kidney disease (CKD), thirty-nine (24.4%) patients had stage 2 CKD, 31(19.4%) patients had stage 3a CKD, thirty-two (20%) patients had stage 3b CKD and six (3.8%) patients had stage 4 CKD. The mean serum creatinine level and eGFR was 1.156±0.53 mg/dl and 68.12±24.39% respectively.

Sixty-two (38.8%) patients had fasting blood sugar level above 140 mg/dl and 107(66.9%) had poor glycemic control with HbA1c levels above 7.5%. Out of 160 patients, sixty-two (38.8%) were having associated hypertension. The mean systolic and diastolic blood pressures of patients were 139.22±15.09

mmHg and 79.0±12.43 mmHg respectively. While examining for other microvascular complications of diabetes we found that 81(50.6%) patients had retinopathy on fundoscopic examination and 99(61.9%) had diabetic neuropathy (Table-I).

Table-I: Baseline characteristics of 160 diabetic patients (n=160)

Categorical Parameters	n(%)
Gender	
Male	82(51.3)
Female	78(48.7)
Age Groups	
30-39 years	6(3.8)
40-49 years	36(22.5)
50-59 years	68(42.5)
60-69 years	26(16.3)
70 years and above	24(15.0)
BMI Groups	
18-24	36(22.5)
25-30	53(33.1)
31-35	48(30.0)
36 and above	23(14.4)
Fasting Blood Sugar Levels	
≤140	98(61.3)
>140	62(38.8)
Albuminuria	
Normal	78(48.8)
Microalbuminuria	20(12.5)
Macroalbuminuria	62(38.8)
Diabetic Kidney Disease Stage	
eGFR Stage 1 (>90)	52(32.5)
eGFR Stage 2 (60-89)	39(24.4)
eGFR Stage 3a (45-59)	31(19.4)
eGFR Stage 3b (30-44)	32(20.0)
eGFR Stage 4 (15-29)	6(3.8)
HbA1c Level	
≤7.5	53(33.1)
>7.5	107(66.9)
Diabetic Retinopathy	
Yes	81(50.6)
No	79(49.4)
Diabetic Neuropathy	
Yes	99(61.9)
No	61(38.1)
Hypertension	
Yes	62(38.8)
No	98(61.3)

**GFR: Glomerular Filtration Rate*

Diabetic nephropathy was found to be most common in 50-59 years' age group i.e., 34 patients followed by 60-69 years age group (Figure). This difference among age groups was statistically significant (p=0.004). We observed that 15 patients with fasting blood sugar (FBS) ≤140 mg/dl and 44 patients with FBS more than 140 md/dl had diabetic nephropathy (p-value <0.001).

While evaluating HbA1c levels we found that there was significant difference in the rate of diabetic nephropathy in patients with HbA1c levels ≤7.5% and >7.5% (p=0.006). Among fifty-nine patients with diabetic nephropathy, 46 had diabetic retinopathy and 47 had neuropathy (p<0.001). We found that patients with diabetic nephropathy had higher mean systolic blood pressure (SBP), mean FBS and longer mean duration of diabetes (p<0.001).

Twenty-one patients had CKD stage 3a (eGFR 45-59%), 32 patients had CKD stage 3b (eGFR 30-44%) and 6 patients with diabetic nephropathy had CKD stage 4 (eGFR 15-29) (p<0.001) (Table-II).

Table-II: Relation of albuminuria and stages of chronic kidney disease (n=160)

		Albuminuria			Total
		<30 (n=78) n(%)	30-299 (n=20) n(%)	≥300 (n=62) n(%)	
eGFR	Stage 1	52(66.7%)	0	0	52
	Stage 2	26(33.4%)	10(50.0%)	3(4.8%)	39
	Stage 3a	0	10(50.0%)	21(33.8%)	31
	Stage 3b	0	0	32(51.6%)	32
	Stage 4	0	0	6(9.7%)	6
Total		78	20	62	160

**GFR: Glomerular Filtration Rate*

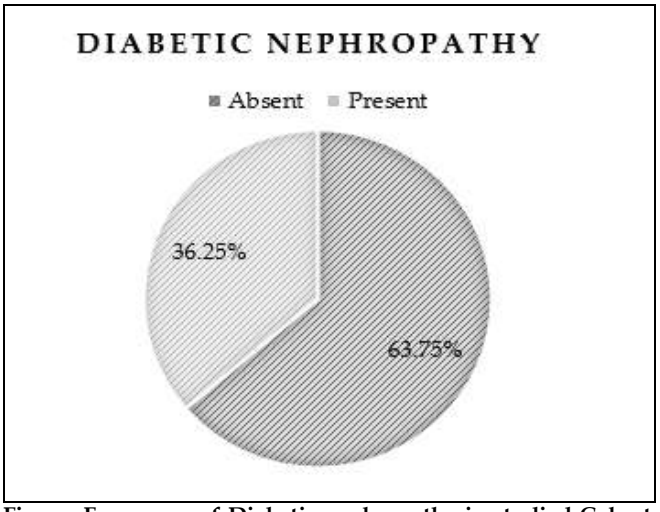

Figure: Frequency of Diabetic nephropathy in studied Cohort (n=160)

DISCUSSION

This study assessed the frequency and baseline characteristics of diabetic nephropathy in type 2 DM patients. Farah et al. studied diabetic individuals with and without diabetic nephropathy including 573(40.99%) men and 825(59.01%) women. Age >60 years, duration of diabetes, HbA1c >%, and hypertension were observed to be associated with DKD (p<0.0001). In addition, DKD was related with retinopathy and neuropathy (p<0.01).[10]

Our study reported the frequency of diabetic nephropathy as 36.9%, much lower than that reported in the US (54%).[11] Contrarily, Kebede *et al.,* while studying newly diagnosed type 2 DM patients, documented that only 13.6% had DN, which is much less than our study.[3] In our study, the prevalence of DN was higher than that reported in a Saudi national diabetes registry-based study (10.8%).[12] A meta-analysis of 30 studies including 79,364 subjects yielded a pooled prevalence of DN of 21.8.[13] The higher prevalence of diabetic nephropathy in our study may be attributable to factors such as suboptimal glycemic control, less frequent screening for diabetic complications, and a longer mean duration of diabetes among our participants.

This study observed normal albuminuria in 78(48.8%) patients, microalbuminuria in 20(12.5%) and macroalbuminuria in 62(38.8%). Among 160 patients, 52(32.5%) patients were having stage 1 chronic kidney disease (CKD), thirty-nine (24.4%) patients were having stage 2 CKD, 31(19.4%) patients had stage 3a CKD, thirty-two (20%) patients had stage 3b CKD and six (3.8%) patients had stage 4 CKD. There was a significant increase in staging in patients with macro-albuminuria; also, most normoalbuminuric patients are stage 1 and stage 2 (p=0.000). Aboelnasr *et al.,* reported similar results i.e., 54.9% of patients had microalbuminuria, 39.2% had macroalbuminuria. As far as eGFR is concerned only 5.2% of patients had eGFR <60 mL/min/1.73,^{2} which is very less compared to our results.[14]

Elhefnawy *et al.,* reported that only 7.9% patients had macroalbuminuria, which is quite less compared to our results.[15] Sana *et al.,* determined the prevalence of microalbuminuria at 25.6% and macro-albuminuria at 4.5%.[16] The American Diabetes Association has recommended screening for diabetic kidney disease (DKD) based on albuminuria and eGFR to avoid missing cases in light of these findings. Variations in the prevalence rate of proteinuria can be caused by differences in study design, sample selection, race, age, diagnostic methods, and approaches to measuring proteinuria and urine collection, length of diabetes, treatment for diabetes, and occurrence of hypertension.

In terms of gender, our results showed that there were 29(49.15%) men and 30(50.8%) women, with no significant difference between the sexes. This is similar to what some other studies have found.[17,18] The prevalence of diabetic nephropathy was related to age, the mean age of the patient was 56.78±7.3 years. Most of the patients were in 50-59 years age group 34(57.6%) (p=0.004). Similarly, Adil *et al.,* found that 10(50%) patients with diabetic nephropathy between 51-60 years.[18]

In our study, the mean duration of diabetes was 8.01±4.596 years. The mean age of diabetic and without diabetic nephropathy patients was 9.73±5.16 years and 7±3.91 years, respectively. This difference was statistically significant, showing that the chances of DN increase with the duration of diabetes (p=0.000). The results were in line with previous research.[19,20] In contrast, Kebede *et al.,* found that the duration of diabetes was inversely correlated with the risk of diabetic nephropathy. Greater than ten years of diabetes lowered the risk of diabetic nephropathy.[3] Upon analyzing previous research, it was revealed that diabetes mellitus goes undiscovered in the majority of the population for a long period of time, and that patients usually comes with established diabetic complications.[21]

We documented that only 20.33% of patients had DN with an HbA1c level below 7.5% and 79.66% with an HbA1c level ≥7.5%. One of the most significant and independent risk factors for DKD is hyperglycemia. It causes the renal function to deteriorate more quickly. Numerous research studies have examined the relationship between nephropathy and glycemic control, revealing a statistically significant association between nephropathy prevalence and higher HbA1c.[22,23] According to a recent meta-analysis, hypertension is significantly linked to the development of diabetic nephropathy. Hypertensive patients are more likely than non-hypertensive patients to develop diabetic nephropathy, as indicated by an odds ratio of 1.67 (95% confidence interval: 13.1–2.14).[24] Similarly, we found a statistically significant relation between hypertension and diabetic nephropathy (p=0.001). Among 59 patients with DN, 33(55.93%) patients were hypertensive, and 26(44%) were non-hypertensive. While evaluating systolic and diastolic blood pressure among diabetic nephropathy, we found that the mean SBP among was 142.71±18.76 mmHg (p=0.025) and 77.20±14 mmHg (p=0.142), respectively. In the study by Farah *et al.,* 69.38% of patients had hypertension, with a mean systolic blood pressure of 135.53 mmHg and a mean diastolic blood pressure of 77.72 mmHg. We found a strong association between DN and BMI. The BMI of type II diabetic patients with and without DN was 34±2.942

kg/m2 and 26.98±4.3 kg/m2, respectively (p=0.000). In the current study, among fifty-nine patients with diabetic nephropathy, 46 had diabetic retinopathy and 47 had neuropathy (p=0.000). Farah *et al.*, documented retinopathy in 477 patients (34.12%).[10]

Different studies, including ours, found significant differences in the prevalence of nephropathy and the risk factors for DKD. These differences could be due to differences in study design and methods used to define the disease, ethnicity, patient selection, and the fact that potentially confounding variables were not controlled for.

LIMITATION OF STUDY

The limitation of current study includes small sample size from a single center and secondly, we enrolled patients from OPD of tertiary care hospital, where most of the patients are referral, resulting in a possibly higher prevalence of Diabetic Nephropathy.

CONCLUSION

The overall rate of diabetic nephropathy among type 2 diabetic patients was 36.9%. Poor glycemic control, duration of diabetes, systolic hypertension, BMI, and serum creatinine were significantly associated with Diabetic nephropathy.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

HI & SWA: Data acquisition, data analysis, critical review, approval of the final version to be published.

AR & MFR: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MA, HAS & IJ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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