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Original Research Article

Study on prevalence of nephropathy in type 2 diabetes mellitus patients and associated factors

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ABSTRACT

Background: Diabetic nephropathy (DN) is the leading cause of end-stage renal disease and the care of patients with diabetes and DN contributes significantly to health care costs. The objective of this present study was to determine prevalence of nephropathy in type2 diabetes and associated factor.
Method: The present cross sectional study was conducted on type 2 diabetic subjects who attended the outpatient and inpatient wards of medicine department in GSL General Hospital from November 2015 to April 2017. Protocol approval was taken from institutional ethical committee and Informed consent from the study subjects was taken.
Result: In this study the overall prevalence of nephropathy in type 2 DM was 44.7% (67 cases). The prevalence of nephropathy was similar in both males (44.3%) and Females (45.1%). and significant association was not found between gender and nephropathy. On apply of chi-square test, association was not found to be statistically significant for Sex (p=0.9), and ECG (p=0.07), whereas association was found to be statistically significant for HbA1C (p=0.04), Dyslipidemia (p=0.006), and USG (p=0.001).
Conclusion: There is significant evidence to support the conclusion that microalbuminuria or proteinuria in patients with diabetes is a potential risk factor not only for kidney function impairment but also a marker for high risk of cardiovascular complications.

Keywords: Electrocardiogram, Nephropathy, Type 2 diabetes mellitus, Ultrasonography

INTRODUCTION

India is the diabetes capital with home to 69.1 million people with DM, the second highest number of cases after China.[1] This global burden of diabetes brings with it the potential for a catastrophic increase in the prevalence of kidney and cardiovascular disease. Although the increased mortality in patients with diabetes traditionally has been attributed to coronary artery disease, more recent studies have emphasized the importance of chronic heart failure (HF) as a common and deadly comorbidity, to which the patient with nephropathy, even in its earliest stages, is especially prone.[2,3]

Diabetic nephropathy (DN) is the leading cause of end-stage renal disease and the care of patients with diabetes and DN contributes significantly to health care costs. Of patients with type 1 diabetes, approx.20%-30% will eventually develop DN, whereas about 10%-20% of those with type 2 diabetes will do so.[4]

Patients with diabetic kidney disease have exceptionally high rates of cardiovascular morbidity and mortality. In fact, the excess mortality among patients with diabetes appears to be largely limited to the subgroup with kidney disease and explained by their high burden of cardiovascular disease. The mechanisms underlying the strong association between diabetic kidney disease and various forms of cardiovascular disease are poorly understood.[5]

The objective of this present study was to determine prevalence of nephropathy in type 2 diabetes and associated factor.

METHODS

The study was a Cross sectional study analysis of all type 2 diabetic subjects who attended the outpatient and inpatient wards of medicine department in GSL General Hospital between 1st November 2015 to 30th April 2017.

Inclusion criteria

All type 2 diabetics above the age of 30 years.

Exclusion criteria

Type 2 diabetics with Ischemic heart disease, Hypertension, Valvular heart disease, UTIS , Poor transthoracic echo window, Known renal disease/family history of renal disease.

Protocol approval was taken from institutional ethical committee and Informed consent from the study subjects was taken.

Data collection procedure

A pre-structured questionnaire was used to collect the clinical data. Baseline data including age, detailed medical history, past history, family history, drug history and personal history were recorded. Clinical examination and routine and relevant investigations were carried out for all participants.

Diagnosis of diabetes was made according to WHO criteria or if the subjects were already taking Insulin or oral anti-diabetic drugs. Criteria for diagnosis of Diabetes mellitus

- Fasting plasma glucose 7.0 mmol (126mg/dl) or
- 2h plasma glucose 11.1 mmol/l (200mg/dl) during an OGTT.[6]

Subjects with systolic pressure more than 130mm Hg and diastolic pressure more than 90 mmHg or those on antihypertensive drugs were considered as hypertensives.

Triglycerides >150mg/dl and HDL<40mg/dl for males and <50mg/dl for females and on specific treatment was taken as dyslipidemia.

Venous blood samples were taken after an overnight fast for fasting blood glucose and 2-hour post glucose blood sugar, glycosylated hemoglobin and lipid profile. Plasma glucose concentration was estimated using the glucose oxidase method. Cholesterol and triglyceride levels were determined in the serum by commercially available kits on an Erbamannheim -360 analyzer .High –density lipoprotein was measured by using the direct high-density lipoprotein method. Low density lipoprotein and very low density lipoprotein cholesterol were calculated according to the formula. LDL cholesterol=cholesterol-[HDL cholesterol+(o.46xtriglycerides)]

Glycosylated hemoglobin (HbA1c) was estimated by ion exchange resin method using colorimetry.

Albumin creatinine ratio (ACR) was measured by immunoturbidimetry using Microalbuminuria test kit provided by ERBA MANHEIM GERMANY. Serum creatinine was done by creatinine enzymatic method; eGFR was calculated using CKD-EPI equation.

Where LAP-left atrial pressure, mitral inflow velocities were traced and the following variables were derived: E/A ratio represents ratio of peak velocity flow in early diastole (E wave) to peak velocity flow in late diastole caused by atrial contraction (A wave), average E/e' represents peak mitral inflow velocity during early diastole to e'-early diastolic velocity, peak TR velocity-pulmonary artery systolic pressure, LA volume index-left atrial volume index.[7]

Statistical Analysis

Categorical variables were presented as numbers and percentages. All descriptive data was expressed as Mean+/- standard deviation and percentages. Chi-square test was used to assess the association among different categorical variables. Correlation was performed to find out the relation between different continuous variables. For all statistical analyses $p<0.05$ was considered statistically significant.

RESULTS

Overall Mean age of study participants was 56.98$\pm$10.27 years with a range from 30 to 88 years. Overall Mean duration of Type 2 Diabetes was 7.65$\pm$5.81 years with a range from 1 to 30 years.

Out of 150 cases, 67 cases (44.7%) had nephropathy and 55.3% did not have nephropathy.

Out of 150 cases, 36 cases (24%) in stage II, 29 cases in stage IV (19.3%) and only 2 cases (1.3%) were in stage

III nephropathy respectively. Around 55% cases do not have nephropathy.

Out of 150 cases, 20% cases were in grade 1-2 and another 19.3% were in grade 2-3. Only one case belonged to grade 3-3.

Table 1: Clinical characteristics.

Characteristics	Frequency	Percentage
Staging of Nephropathy		
Stage – 2	36	24
Stage – 3	2	1.3
Stage – 4	29	19.3
USG findings		
Grade 1-2	30	20.0
Grade 2-3	29	19.3
Grade 3-3	1	0.7
NAD	90	60.0
ECG finding		
Left Ventricular Hypertrophy	51	34.0
Normal	99	66.0

Out of 150 cases, 51 cases (34%) showed left ventricular hypertrophy on ECG.

On apply of chi-square test, association was not found to be statistically significant for Sex (p=0.9), and ECG (p=0.07).

Table 2: Association between different parameters with Nephropathy status.

Variable	Nephropathy Status			
	Present	Absent	Chi-square-value	p-value
Sex				
Female	32(45.1)	39(54.9)	0.009	0.9
Male	35(44.3)	44(55.7)		
HbA1C				
< 7.5	4 (22.2)	14(77.8)	4.2	0.04
> 7.5	63(47.7)	69(52.3)		
Dyslipidemia				
Absent	22(32.4)	46(67.6)	7.63	0.006
Present	45(54.9)	37(45.1)		
USG				
Grade 1-2	30 (100)	0	123.88	0.001
Grade 2-3	29 (100)	0		
Grade 3-3	1 (100)	0		
NAD	7 (7.8)	83(92.2)		
ECG				
LVH	28(54.9)	23(45.1)	3.3	0.07
Normal	39(39.4)	60(60.6)		

On apply of chi-square test, association was found to be statistically significant for HbA1C (p=0.04), Dyslipidemia (p=0.006), and USG (p=0.001)

Table 3: Comparison of study variables and nephropathy.

Variable	Nephropathy status			
	Present	Absent	t-value	p-value
Age	58.57±10.37	55.70±10.07	1.71	0.09
Duration of T2DM	10.70±6.83	5.19±3.17	6.5	0.001
Height	160.54±7.25	159.81±8.007	0.58	0.5
Weight	64.60±10.2	67.88±12.9	-1.69	0.09
BMI	25.03±3.74	26.49±4.52	-2.11	0.04
Waist circumference	88.85±8.83	87.09±10.23	1.11	0.3
WHR	0.86±0.09	0.92±0.11	-3.77	0.001
Hb	10.17±1.60	10.98±1.77	-2.93	0.004
FBS	175.61±55.03	164.13±35.04	1.55	0.1
PPBS	269.01±84.4	246.73±57.9	1.91	0.05
HbA1C	9.09±1.02	9.12±1.58	-0.14	0.88
UACR	84.56±10.4	70.77±5.38	9.52	0.0001
Serum creatinine	2.51±0.84	1.37±0.23	10.94	0.003

On unpaired t test, difference was not found to be statistically significant for Age (p=0.09), Height (p=0.5), Weight (p=0.09), Waist circumference (p=0.3), FBS (p=0.1), and HbA1C (p=0.88).

On unpaired t test, difference was found to be statistically significant for Duration of T2DM (p=0.001), this shows that cases with more duration of type 2 DM had more risk of nephropathy, BMI (p=0.04), WHR(p=0.001), Hb

(p=0.004), PPBS (p=0.05), UACR (p=0.0001), and Serum creatinine (p=0.003).

DISCUSSION

The prevalence in our study was 44.7% with a study population of 150 diabetic cases. which was compared to other studies like CURE study where the prevalence was 29.1%, 39% in study group, it was 29, 33% study group, 25.95% in study group, in a Thailand study by prevalence was 37.2%.[8-13]

It was clear that there was a high prevalence of diabetic nephropathy in the present study group compared to other study groups, which may signify that rise in diabetic population and early identification of nephropathy through microalbuminuria was needed.

Age distribution in Type 2 diabetics with nephropathy

In the present study group the mean age of the population with diabetic nephropathy was 58±10 years (p=0.08) and was compared to other study groups like cure study by Unnikrishnan et al where the mean age was 52±11 years, In a south Asian study mean age was 54.4±9.3 years, Indian study mean age was 53.78±4.28 years, Indian study mean age was 49.48±11.90 year, a Japanese study mean age was 61±12 years, (UKPDS 74) it was 52.4±8.8 years, a study mean age was 49 years. By this the mean age of the population with nephropathy compared to other studies was more commonly above 50 years.[8,9,11,14,15]

Gender distributions in Type 2 diabetics with nephropathy

In the present study group prevalence of nephropathy in females was 45.1% and in males was 44.3% (p=0.925) and was compared with other study groups like CURE study by prevalence in males was 48.7% (p=0.181), in a south Asian study by prevalence in males was 45.2% (p=0.65), in a Japanese study by alprevalence in males was 58% (p=0.09), (UKPDS 74) study prevalence of males was 59% (p=0.045), except for the Retnakaran et al study the other study groups were showing no significant association with either sex. The present study was in correlation with studies showing no significant association with either sex.[10,16]

Duration of diabetes in type 2 diabetics with nephropathy

Duration of diabetes was associated with increased prevalence of nephropathy which was statistically significant (p=0.001), where the mean duration of diabetes was 10.70±6.83 years. This was compared with other study groups like cure study by Unnikrishnan et al where the duration of diabetes of 5±6 years was associated with microalbuminuria (p<0.0001) and the duration of diabetes of 10±6 years was associated with macro albuminuria (p<0.0001)[8], in a study by (UKPDS 74) where the patient was observed for a median period of 15 years and 40% developed albuminuria and 30% developed renal impairment, Study found no correlation between duration of diabetes and nephropathy 11.9±0.4 years (p=0.56), in a Japanese study duration of diabetes showed significant correlation with eGFR (p<0.001) and there was no correlation between duration of diabetes and albuminuria.[10,16]

It shows that majority of the population with longer duration of diabetes mellitus had increased prevalence of nephropathy in type 2 diabetes patients. Increased risk of microvascular complications was associated with longer duration of diabetes.

Obesity indices BMI and WHR in Type 2 diabetics with nephropathy

In the present study group majority of the patients belonged to the overweight category with mean BMI 25.03±3.74 kg/m^2(p<0.037) and with mean waist circumference 88.85±8.83 cm (p=0.267) and with mean WHR 0.86±0.09 (p<0.001), which shows a significant association between the BMI and WHR with diabetic nephropathy where waist circumference did not show any significant association with nephropathy.

The above data was Compared with the other study groups like CURE study by Unnikrishnan et al where it shows a mean BMI of 23.6±5 kg/m^2 (p=0.004) and mean waist circumference was 91+10 cm (p=0.864), in a study by Sanjeev Kumar et al mean BMI was 26.93+2.31 kg/m^2 (p=0.0015), in a study done mean BMI was 25.72+3.448 kg/m^2 (p=0.04), in a study done BMI was 29.8 kg/m^2, in a study done (UKPDS 74) mean BMI was 27.5±5.4 kg/m^2 and waist circumference mean was 95±13 cm, in a study done. waist hip ratio was not significantly associated with nephropathy, in a study done mean BMI was 25.2±5.2 kg/m^2 which showed significant association with albuminuria (p=0.04) but not significantly associated with eGFR (p=0.3). [8-10,15-17]

The study showed majority of patients was in overweight and obese category and was also significantly associated with diabetic nephropathy.

Glycemic indices FBS, PPBS, HbA1C in type 2 diabetics with nephropathy

In the present study majority of patients had higher FBS, PPBS and HbA1C values, the mean FBS value was 175.6±55.03 mg/dl (p=0.123), and the mean PPBS value was 269.01±84.4 mg/dl (p=0.05), and the mean HbA1C value was 9.09±1.02 %, when HbA1C compared with <7.5% and >7.5% (p<0.05) and it was statistically associated with diabetic nephropathy.

The above data has been compared with other studies like CURE study by Unnikrishnan et al where the mean FBS was 183.6±70.2 mg/dl (p<0.0001) and the mean HbA1C

was 9.5±2.3 % (p<0.0001), in a study by Sanjeev Kumar et al where the mean FBS was 211.52±27.85 mg/dl (p<0.0001), mean HbA1C was 8.37±0.83 %, (p<0.0001), in a study where the mean FBS was 147.6 mg/dl (p<0.0001) and the mean HbA1C was 6-8% (p=0.0004), in a study where the mean FBS was 230.81±111.66 mg/dl (p=0.21), the mean PPBS was 362.24±143.02 mg/dl (p=0.01), the mean HbA1C was 8.9±2.4 (p=0.02), in a study by where the mean HbA1C was 7-9 % (p=0.3)[9], in a Japanese study HbA1C when compared with eGFR (p=0.008) and albuminuria (p=0.03) there was significant association seen. [8,10,14-16]

There was significant association between the high glycemic indices like HbA1C in type 2 diabetics with nephropathy and high values of FBS and PPBS were present but not significantly associated with nephropathy. This shows that uncontrolled hyperglycemia had increased risk for nephropathy in type 2 diabetes patients.

Dyslipidemia in type 2 diabetics with nephropathy

In the present study group the prevalence of dyslipidemia or abnormal lipid levels in diabetics was 54.7% and in Type 2 diabetics with nephropathy it was 54.9% (p=0.006) which shows a significant association between dyslipidemia and nephropathy.

The above data was compared with other studies like where there was a prevalence of 81.5% with abnormal lipid levels in patients with diabetic nephropathy, this was also compared with another study where elevated serum lipids was a risk factor for the development of diabetic nephropathy, in another study where the total cholesterol (p=0.01), LDL cholesterol(p=0.009) and triglycerides (p=0.224) were higher in microalbuminuria group than normoal buminuria group and the differences were statistically highly significant except for HDL in males (p=0.154) and triglycerides(p=0.224), in a study by there was no significant association between abnormal lipid levels and nephropathy, in a study (UKPDS 74) where dyslipidemia (total cholesterol (p=0.04), HDL cholesterol (p=0.02), LDL cholesterol (p=0.08), triglycerides (p<0.0001)) had a significant association with albuminuria or nephropathy, in a Japanese study by dyslipidemia has no significant association with eGFR (p=0.26) but had a significant association with albuminuria (p<0.005).[9,10,15,16,18,19]

The present study shows that abnormal elevated serum lipid levels or dyslipidemia had a significant association with diabetic nephropathy.

Renal parameters UACR, serum creatinine, and eGFR in Type 2 diabetics with nephropathy

In the present study group mean urine albumin creatinine ratio (UACR) was 84.6±70.8 mg/g (p=0.0001), and the mean serum creatinine was 2.51±1.37 mg/dl (p=0.003), and the mean eGFR was 37.54±24.9 ml/min/m^2 (p=0.001), which shows that the renal parameters which were mentioned shows statistically significant association with the nephropathy.

The above data was compared with other studies like DCCT where gender specific equations of ACR shows a cut off of micro albuminuria and macro albuminuria in males was 19.1 mg/g and 143.5 mg/g, in females was 29.0 mg/g and 217.4 mg/g, and eGFR mean was 84.5±17.1 ml/min/m^2 (p<0.001), and serum creatinine mean was 0.95±0.3 mg/dl (p<0.001), and these values are found to be significantly associated, in a study by Fisher et al the mean eGFR was 43±13 ml/min/m^2 and median ACR was 46 mg/g, in a Japanese study the mean ACR with respect to albuminuria was 261.5 mg/g (p<0.001), and with respect to eGFR strata it was not significantly associated, and in that study mean eGFR and mean serum creatinine when compared to eGFR strata they were significantly associated but with respect to albuminuria they were not significantly associated, in various other studies like mean serum creatinine was 1.76±0.59 mg/dl (p<0.0001) and was significantly associated with nephropathy, in mean serum creatinine was 1.08±0.18 mg/dl (p=0.01) and shows a significant association with nephropathy, mean serum creatinine was 0.86 mg/dl and shows significant association with macro albuminuria (p=0.00093) and not significantly associated with microalbuminuria (p=0.20), south Asians showed an eGFR of 100ml/min and Europeans showed an eGFR of 90ml/min/m, in CURE study ACR showed a significant association with macro albuminuria (p=0.043) but not significantly associated with microalbuminuria. studied role of eGFR in chronic kidney disease in predicting prognosis, eGFR was one of the important indicator of reserved renal function and indicator of prognosis.[9,8,14-16,22]

Rise in UACR and serum creatinine and a decline in eGFR shows a significant association with diabetic nephropathy. This may be related to longer duration of diabetes and its complications.

Ultrasonography renal parenchymal changes in Type 2 diabetics with nephropathy

In the present study majority of the cases with nephropathy shows renal parenchymal changes on ultrasonography, 60 out of 67 cases (89.5%)with nephropathy showed renal parenchymal changes on USG, which was significantly associated (p=0.001).

The above data was compared with other studies showed that 80% of the study population had renal parenchymal changes on ultrasonography which showed a linear relationship between declining eGFR and increasing serum creatinine. In a study done where the diabetic patients with chronic renal failure with raised intrarenal resistive index by ultrasonography and color Doppler of the renal system showed that most of the patients were generally older with high proteinuria and higher

creatinine levels and with longer duration of diabetes and also presented with a higher rate of renal failure requiring dialysis, The echogenicity of the renal parenchyma was correlated with glomerular and interstitial findings. There was a significant correlation between echogenicity of the renal parenchyma and prolonged pathological processes of the renal parenchyma. A Diabetes influences renal vascularity and alter Doppler indices such as resistive index (RI) values. This finding was also consistent with. Showed the grading of renal echogenicity on sonography correlated well with serum creatinine and was statistically significant positive correlation ($p<0.001$). [23-28]

USG evidence of renal parenchymal changes was significantly associated with diabetic nephropathy. It is a reliable and inexpensive tool to predict nephropathy.

Electrocardiographic evidence of left ventricular hypertrophy in Type 2 diabetics with nephropathy

In the present study 54.9% of nephropathy patients had left ventricular hypertrophy and it was not significantly associated. This was compared with other studies like where 77.6% of diabetic nephropathy patients had left ventricular hypertrophy and the LVMI was significantly associated with eGFR ($p<0.05$) study the patients with type 2 diabetes with chronic kidney disease showed left ventricular hypertrophy with significant association to the severity of chronic kidney disease, in study the rate of LVH was significantly higher in patients with early diabetic kidney disease than those without (57% vs 32.9%; $P<0.001$), in F.S Nielsen et al study showed that prevalence of LVH was more in non-insulin dependent diabetes mellitus patients with diabetic nephropathy than others without nephropathy.[29-32]

An increased prevalence of LVH in diabetics with nephropathy but it was not significantly associated. This shows that nephropathy had implications over cardiovascular outcomes.

Anemia in type 2 diabetics with nephropathy

In the present study the mean hemoglobin was 10.17 ± 1.60 g/dl ($p=0.004$) and it was significantly associated with diabetic nephropathy. This was compared with other studies where anemia was found in early kidney disease, and declining Hb levels were more common among those with higher levels of albuminuria, inone in five patients with diabetes and stage 3 CKD had anemia and its severity worsens with more advanced stages of CKD and in those with proteinuria, in Keane WF et al. study where they evaluated (RENAAL) study of patients with type 2 diabetes and nephropathy, and showed that anemia at the start of the study was a strong predictor of the rate of doubling of serum creatinine or development of ESRD, in study showed that anemia was a common complication of diabetic renal disease, seen with a two to three times greater prevalence and earlier onset than in patients with renal impairment from other causes, In a low hemoglobin predicted loss of GFR even in the absence of overt proteinuria.[33-37]

Low hemoglobin which means anemia was a common complication of diabetic nephropathy and it was significantly associated.

In the present study there was significant correlation between Duration of Type 2 Diabetes, BMI, WHR, HbA1c <7.5% and >7.5%, UACR, serum creatinine, eGFR, dyslipidemia, Hb, USG showing renal parenchymal changes, and diastolic dysfunction with nephropathy.

CONCLUSION

Results of the present study reveals that there is significant evidence to support the conclusion that microalbuminuria or proteinuria in patients with diabetes is a potential risk factor not only for kidney function impairment but also a marker for high risk of cardiovascular complications.

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