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A Study of Relationship between Diabetic Nephropathy and Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure among Patients

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ABSTRACT
Diabetes mellitus (DM) has emerged as a significant worldwide health issue. One of the most significant long-term microvascular consequences of diabetes mellitus (DM) is type 2 diabetic nephropathy (T2DN), which is a major contributor to end-stage renal disease (ESRD) at the global level. Diabetic nephropathy is a mild inflammatory condition which is linked with many other types of diseases and can cause a lot of other diseases to generate in our body. So, the objective of this study is to find the degree of correlation between Diabetic Nephropathy and Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure among Patients. For this purpose, two group of patients were taken; one as an experimental group and one as a controlled group. A total of 68 patients were taken as sample for both the groups. Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure were assessed in both the groups. The data was analysed using SPSS version 16.0. Mean, SD, Chi-square test, Unpaired t-test were calculated to find the relationship between Diabetic Nephropathy and Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure among Patients. The study concluded that there is a high degree of correlation between the Diabetic Nephropathy and Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure among Patients.

Keywords: *Blood Pressure, Blood Sugar, Diabetic Nephropathy, Hs-CRP, Lipid Profile.*

1. INTRODUCTION

Diabetic nephropathy, also known as diabetic kidney disease, is a serious complication of diabetes where kidney damage occurs due to high blood sugar levels, leading to the kidneys' inability to filter waste and fluid effectively, potentially leading to kidney failure. Early treatment may prevent this condition or slow it and lower the chance of complications. Diabetic nephropathy happens when diabetes damages blood vessels and other cells in the kidneys. According to one study, a third of people show high levels of albumin in their urine after a diagnosis of diabetes. However, fewer than half of these people will develop full nephropathy. Statistics have suggested that kidney disease is uncommon in people who have had diabetes for less than 10 years. Also, if a person has no clinical signs of nephropathy 20–25 years after diabetes starts, they have a low chance of developing it thereafter. Diabetic nephropathy is less likely if a person with diabetes manages their glucose levels effectively.

Earlier Diabetic Nephropathy was not thought of as an inflammatory illness. However, according to current research, the development and progression of DN are aided by kidney inflammation. The established metabolic, biochemical, and hemodynamic abnormalities in the diabetic kidney may be a major component that activates inflammation.

According to studies, those who develop diabetic nephropathy have low-grade inflammation for years before the disease manifests itself. Numerous human investigations have confirmed similar results, and numerous cross-sectional studies have shown an association between diabetic nephropathy and elevated levels of inflammatory markers such Lipid Profile, Hs-CRP, Blood Sugar and Blood Pressure.

2. REVIEW OF RELATED LITERATURE

Liu et al (2015) studied the association between high-sensitivity C-reactive protein (hs-CRP) concentration and diabetic nephropathy (DN). They systematically searched PubMed, Medline and Embase databases up to September, 2014 for the relevant studies. A total of 11 studies containing 1331 cases and 1779 controls were included in this study. Significant heterogeneities were observed in our results. The result of meta-analysis showed that the hs- CRP concentrations in DN

patients were significantly higher than that in controls of healthy people and diabetes mellitus (DM) patients without nephropathy. In addition, the hs-CRP concentration in macroalbuminuria (D3) group was significantly higher than that in microalbuminuria (D2) group and non-albuminuria group (D1). Sensitivity analysis revealed that the results were stable. As well, no publication bias was observed in our results. They concluded that hs-CRP concentration could be an indicator of DN in DM patients.

Soni et al (2016) investigated if there was any relation of inflammatory markers in the development and progression of albuminuria in diabetic nephropathy patients. The study was a cross-sectional type of study carried out in Medicine Department of TMMC & RC, Moradabad. A total of one hundred fifty (150) patients suffering with diabetes mellitus were selected for the study. HS-CRP was significantly high in microalbuminuria compare to normoalbuminuria. Whereas, HS-CRP was significantly high in macroalbuminuria compare to microalbuminuria diabetic nephropathy patients. IL 6 was significantly high in microalbuminuria diabetic nephropathy patients compare to normoalbuminuria. Whereas, IL 6 was significantly high in macroalbuminuria diabetic nephropathy patients compare to microalbuminuria diabetic nephropathy patients. The study concluded that higher level of inflammatory markers like CRP and IL 6 might be an additional factor in the pathogenesis of development of diabetic nephropathy along with traditional metabolic factors.

Chauhan et al (2017) investigated the role of subclinical inflammation in the pathogenesis of diabetic nephropathy by evaluating the association between the serum High-sensitivity CRP (hsCRP) (marker of inflammation) and urinary albumin to urinary creatinine ratio. A prospective case control study of 100 diabetic patients were taken (50 patients with nephropathy and 50 without nephropathy) all these patients hsCRP was compared with UACR (urine albumin to urine creatine ratio). Mean hsCRP in patients without nephropathy was 1.7046 mg/dL and Mean hsCRP in patients with nephropathy was 8.83054. This difference was found to be statistically significant (p value<0.0001). Mean hsCRP in patients without macro albuminuria was 4.51±6.34. Mean hsCRP in patients with macro albuminuria was 8.71±3.99. This difference was found to be statistically significant (p value= 0.0089).

Kumar and Krishnan (2018) determined serum high sensitivity C-reactive protein (hs-CRP) and urine albumin creatinine ratio (UACR) in patients with type 2 DM and evaluated the relationship of hs-CRP with UACR as markers of early kidney damage. Cross sectional study which included 95 clinically diagnosed type 2 DM patients of age group 40 to 70 years. Spot urine microalbumin and creatinine were estimated by immunoturbidimetry and Jaffe method respectively, and the results were reported as albumin creatinine ratio (mg/g). The mean hs- CRP was higher in diabetic patients with microalbuminuria (7.28 ± 3.46) comparing to diabetic patients without microalbuminuria (1.04 ± 0.85) and was statistically significant (p< 0.001). The Pearson correlation test showed a positive correlation between hs-CRP level and UACR level (r = 0.41; P =0.02). The study concluded that microalbuminuria was accompanied by elevated hs-CRP level suggesting activation of inflammatory pathways in development of kidney disease. So as a screening method, measurement of serum hs-CRP along with urine albumin creatinine ratio helped in diagnosing early stages of diabetic nephropathy.

Singh (2019) evaluated the correlation of inflammatory marker High-sensitive C-reactive protein with risk factors of nephropathy in type 2 diabetes. 82 type 2 diabetes patients (T2DM) were selected to conduct the observational study. A standard questionnaire was used to collect the data regarding major environmental risk factor for diabetic nephropathy of T2DM like age, duration of diabetes, smoking, anti-diabetic medication and anti-hypertensive medication. Blood sample was collected to perform pathological test like Fasting Plasma Glucose (FPG), Post Prandial Plasma glucose (PPG) and high sensitive C reactive protein (Hs-CRP). Result of this observational study reveals that the risk factors for diabetic nephropathy of T2DM like age (p=0.231), duration of diabetes (p=0.342), smoking (p=0.931), anti-diabetic medication (p=0.537) and antihypertensive medication (p=0.425) was not found to be correlated with Hs- CRP levels. The study concluded that inflammatory marker High-sensitive C-reactive protein insignificantly correlated with the major environmental risk factor for diabetic nephropathy of T2DM like age, duration of diabetes, smoking, anti-diabetic medication and anti-hypertensive medication.

Prabha et al (2020) determined an earlier pathogenic marker for DN among T2DM patients. The cross-sectional study was conducted among 92 clinically diagnosed T2DM patients. Mean serum hs-CRP value of diabetic subjects with microalbuminuria was 6.9±3.2 mg/L and diabetic subjects without microalbuminuria was 1.4±0.68 mg/L. There was a positive correlation between hs-CRP and Urine Albumin Creatinine Ratio (UACR) (r=0.47; p=0.02). There was also a positive correlation between hs-CRP and FBS levels and hs-CRP and duration of type 2 diabetes mellitus. The hs-CRP and UACR were elevated among type 2 diabetic patients. There was a positive correlation between hs-CRP and FBS and duration of diabetes mellitus. The study concluded that as hyperglycemia played a critical pathogenic role in type 2 diabetes through the inflammatory pathway, hs-CRP might be suggested as a developmental biomarker of DN among T2DM patients in association with UACR.

Tang et al (2022) identified the correlation between hs-CRP levels and diabetic kidney disease (DKD) in patients with type 2 diabetes mellitus (T2DM). The cross-sectional and observational study included 927 patients with T2DM. In total, 927 patients were recruited in our study. The median age of the recruited patients was 55 years, and there were 346 female patients

and 581 male patients. The hs-CRP levels were evidently higher in patients with DKD than those without DKD. After adjusting for age, sex, diastolic blood pressure, systolic blood pressure, body mass index, neck circumference, waist circumference, hypertension, duration of diabetes, common carotid artery plaque, fasting plasma glucose, glycated hemoglobin, hemoglobin, erythrocyte, leukocyte, γ-glutamyl transferase, albumin, urea nitrogen, uric acid and triglyceride, a significant increase in the odds ratios (ORs) for DKD in the fourth hs-CRP quartile compared with the first quartile was observed (P value for trend= 0.003), and the ORs (95% confidence intervals) in the fourth quartile of hs-CRP were 1.968 (1.244–3.114) for DKD compared to the first quartile.. Moreover, the RCS curves presented a positive association between hs-CRP and DKD in total subjects, male subjects and female subjects, respectively. The study concluded that hs-CRP levels were significantly and positively correlated with the presence of DKD which might provide predictive and diagnostic values in clinical practice.

Sanchez-Alamo et al (2022) evaluated the association between IL-6 levels and progression of DKD in patients with type 2 diabetes mellitus. IL-6 levels were measured at baseline and after 4 and 12 months in 70 patients included in a multi-center, randomized controlled clinical trial designed to compare the effect of RAS blockers in monotherapy to dual blockade for slowing the progression of DKD. The median follow-up was 36 months, during which 27 patients (38.6%) reached the primary endpoint. Baseline IL-6 levels correlated with TNF-α, C-reactive protein, and PTH levels. Survival analysis showed that patients with the highest IL-6 levels (> 4.84 pg/mL) reached the primary endpoint faster than the other two groups. Multivariate Cox regression analysis showed that baseline IL-6 levels > 4.84 pg/mL (HR 4.10, 95% CI 1.36 - 12.31) were a risk factor for reaching the primary endpoint adjusted for eGFR and proteinuria. Generalized linear mixed model analysis showed no effect on subsequent IL-6 levels either with RAS blockade monotherapy or dual blockade. The study concluded that treatment with RAS blockade did not influence IL-6 levels. IL-6 was independently associated with an increased risk for progression of DKD.

Lin et al (2023) evaluated the causality between hsCRP and DN based on Mendelian randomization (MR) analysis. A total of 2332 participants with type 2 diabetes from the Taiwan Biobank database was analyzed. The analyses of the observational study showed that the hsCRP level was significantly associated with DN after multivariate adjustment (adjusted OR 1.15; 95% CI 1.01 to 1.32). Unweighted/weighted GRSs for log-transformed hsCRP satisfied MR assumptions 1 and 3, respectively; that is, a significant association with hsCRP was observed but that with DN was absent (adjusted OR 1.00, 95% CI 0.92 to 1.09; 1.00, 0.72 to 1.39, respectively). The MR analyses demonstrated that a 1- unit increase in the log- transformed genetically predicted hsCRP by unweighted and weighted GRSs was associated with DN, demonstrating ORs of 1.80 (95% CI 1.51 to 2.14) and 1.67 (95% CI 1.40 to 1.98), respectively. The study concluded that hsCRP level was causally related to DN.

3. OBJECTIVES

This research papers handles the following objectives:

i. To study the relationship between Diabetic Nephropathy and Lipid Profile among Patients.

ii. To study the relationship between Diabetic Nephropathy and Hs-CRP among Patients.

iii. To study the relationship between Diabetic Nephropathy and BMI among Patients.

iv. To study the relationship between Diabetic Nephropathy and Blood Pressure among Patients.

4. HYPOTHESES

This research papers handles the following objectives:

v. There is a positive relationship between Diabetic Nephropathy and Lipid Profile among Patients.

vi. There is a positive relationship between Diabetic Nephropathy and Hs-CRP among Patients.

vii. There is a positive relationship between Diabetic Nephropathy and Blood sugar among patients.

viii. There is a positive relationship between Diabetic Nephropathy and Blood Pressure among Patients.

5. MATERIAL AND METHODS

Study site: Department of Internal Medicine, Indraprastha Apollo Hospital, New Delhi

Study design: Case-control study

Study participants: Patients with diabetic nephropathy as cases and without diabetic nephropathy served as controls

Study period: September,2022 to January,2024

Sample Size:

For the margin of error at 5% and confidence level of study at 95%, a minimum of 34 patients (considering 2.2% prevalence rate of nephropathy among type-2 diabetic patients from previous studies) are required to study the role of subclinical inflammation in type 2 diabetic patients having nephropathy. Considering the case control study design, a total of 68 patients (34 case and 34 control) will be required for this study.

Sample Size Justification:

Study used (Unnikrishnan et al, 2007)[77]: Formula for calculating the sample size -

$n= z^2 \times p(1-p)/e^2$

Where,

n is sample size z is the z score

e is the margin of error

p is the population proportion

n = (1.96*1.96) x (0.022*(1-0.022))/(0.05*0.05) = 34

INCLUSION CRITERIA:

1. Patients of type 2 diabetes.
2. Patients with albuminuria

EXCLUSION CRITERIA:

1. Current acute illness including infectious diseases with in past 1 week.
2. Cigarette smoking.
3. Active immunological diseases.
4. Confounding factors for proteinuria like severe uncontrolled hypertension (>160/100)
5. Malignancy.

Methodology: Institutional ethical committee approval for the study was taken.

- A detailed history was taken and the following details recorder: age, sex, duration of diabetes, mode of detection of diabetes, treatment, family history of diabetes, hypertension, cardiovascular and cerebrovascular disease.
- The patients were thereafter subjected to a detailed physical examination with special emphasis on blood pressure, retinopathy, height, weight, BMI, waist circumference, hip circumference, waist-hip ratio.
- Lab investigations included:

Complete hemogram	Plasma glucose-fasting and postprandial
Kidney function test (KFT)	Urine routine/ microscopy
HbA1c, UAE,hs-CRP	Chest X-ray
Lipid profile	ECG with rhythm strip

- Blood Urea was estimated by Diacetyl monoxime method and modified Jaffe's method was used for estimation of serum creatinine.
- Fasting blood sugar was measured with capillary sugar levels using strip glucometer and Glycated haemoglobin (HbA1c) was measured using ion exchange chromatography method.
- Highly sensitive CRP (hs-CRP) was measured by means of an ultrasensitive solid phase enzyme linked immunosorbent assay (Calbiotech Inc., CA, USA).
- Urinary albumin was quantified by using colorimetric method and urine dipstick test was also done for proteinuria.

Criteria for the Diagnosis of Diabetes Mellitus:

- Symptoms of diabetes plus random blood glucose concentration 11.1 mmol/L (200 mg/dL) [a]

or

- Fasting plasma glucose 7.0 mmol/L (126 mg/dL)[b] *or*
- A1C >6.5% [c] *or*
- Two-hour plasma glucose 11.1 mmol/L (200 mg/dL) during an oral glucose tolerance test[d]

Criteria of diagnosis of microalbuminuria:

The term microalbuminuria refers to urinary excretion of very small amounts of albumin 30- 300 mg/day or 20-200 µgm/min or albumin creatinine ratio of 30-300µgm/mg or mg/gm and it represents 1st laboratory evidence of diabetic nephropathy.

Statistical Methods:

The results are presented in frequencies, percentages and mean±SD. The Unpaired t-test followed by Tukey's pairwise comparison tests was used to compare continuous variables. The Chi-square test was used to compare continuous variables. The Pearson correlation coefficient was calculated. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

Data Collection: Data was collected and the proforma is attached in the annexure. Personal interviews and review were done to acquire the relevant information from the patient or the relatives. Lab values of the test performed was taken from the hospital facility

6. RESULTS AND OBSERVATIONS

The following results were obtained from the study:

Table-1: Distribution of age between the groups

Groups	**Age in years (Mean±SD)**
Cases	51.74±8.67
Controls	51.26±8.13
p-value[1]	0.81

[1]Unpaired t-test

Table-1 shows the distribution of age between the groups. The mean age of cases and controls was 51.74±8.67 and 51.26±8.13 years respectively. There was no significant (p>0.05) difference in age between the groups showing comparability of the groups in terms of age.

Table-2: Distribution of gender between the groups

Gender	**Cases (n=34)**		**Controls (n=34)**		**p-value[1]**
	No.	**%**	**No.**	**%**	
Male	16	47.1	16	47.1	1.00
Female	18	52.9	18	52.9	

[1]Chi-square test

Table-2 shows the distribution of gender between the groups. The percentage of male and females were similar in both the groups.

Table-3: Comparison of Lipid profile between the groups

Lipid profile	**Cases (n=34)**	**Controls (n=34)**	**p-value[1]**
Cholesterol	225.18±16.07	180.94±20.87	0.0001*
TG	177.50±18.05	133.94±22.26	0.0001*
HDL	45.00±8.79	38.82±10.71	0.01*
LDL	117.00±8.41	119.94±9.21	0.17

[1]Unpaired t-test, *Significant

Table-3 shows the comparison of lipid profile between the groups. Cholesterol, TG and HDL were significantly ($p<0.05$) increased among cases than controls.

Table-4: Comparison of hsCRP between the groups

	Cases (n=34)	**Controls (n=34)**	**p-value[1]**
hsCRP	6.96±2.13	3.13±2.15	0.0001*

[1]Unpaired t-test, *Significant

Table-4 shows the comparison of hsCRP between the groups. hsCRP was significantly (p=0.0001) increased among cases (6.96±2.13) than controls (3.13±2.15).

Table-5: Comparison of blood sugar between the groups

Blood pressure	**Cases (n=34)**	**Controls (n=34)**	**p-value[1]**
FBS	183.12±18.32	84.09±14.74	0.0001*
PPBS	300.65±60.86	132.97±19.86	0.0001*

[1]Unpaired t-test, *Significant

Table-5 shows the comparison of blood sugar between the groups. Both FBS and PPBS were significantly (p=0.0001) higher among cases compared to controls.

Table-6: Comparison of blood pressure between the groups

Blood pressure	**Cases (n=34)**	**Controls (n=34)**	**p-value[1]**
SBP	133.94±6.54	119.94±6.37	0.0001*
DBP	86.65±6.35	70.24±5.15	0.0001*

[1]Unpaired t-test, *Significant

Table-6 shows the comparison of blood pressure between the groups. Both SBP and DBP were significantly (p=0.0001) higher among cases compared to controls.

7. CONCLUSION

As a result, it was shown from this study that hs-CRP was related to early development of diabetic nephropathy and thus doctors may use hs-CRP as an independent indicator for the same. Potentially, hs-CRP can act as a biomarker for the emergence of diabetic nephropathy. The study showed that Cholesterol, TG and HDL were significantly increased among cases than controls. hsCRP was significantly increased among cases than controls. FBS, PPBS, SBP and DBP were significantly higher among cases compared to controls.

LIMITATION OF THE STUDY

This is a tertiary private hospital-based study with a small sample size.

RECOMMONDATIONS

The studies with larger sample size are recommended to have more robust findings.

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