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## A Case: Control Study On Determinants Of Diabetic Nephropathy In Type II Diabetic Patients And Its Effect On Quality Of Life In Tertiary Care Hospital.

Taheseen Fatema Shaikh<sup>1</sup>, Pallavi Shelke<sup>2\*</sup>, Dhanashree Khade<sup>3</sup>, and Seema Bansode Gokhe<sup>4</sup>.

<sup>1</sup>Senior Resident, Department of Community Medicine, LTMMC & GH, Sion, Mumbai, Maharashtra, India.

<sup>2</sup>Professor (Additional), LTMMC and GH, Sion, Mumbai, Maharashtra, India.

<sup>3</sup>Assistant Professor, Dept. of Community Medicine, LTMMC and GH, Sion Mumbai, Maharashtra, India.

<sup>4</sup>Professor and Head, Dept. of Community Medicine, LTMMC and GH Sion, Mumbai, Maharashtra, India.

### ABSTRACT

Non-communicable diseases (NCDs) pose a significant threat to health and kill 41 million people annually, accounting for 71% of global deaths. Cardiovascular diseases are the most common, accounting for 17.9 million deaths annually. Cancers, respiratory diseases, and diabetes account for over 80% of premature NCD deaths. Diabetes Mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbance of carbohydrates, fat and protein metabolism resulting from defect in insulin secretion, insulin action or both. The present study was conducted in 1400 bedded tertiary care hospital with medical colleges in a metropolitan city. This tertiary care hospital has six units in internal medicine department and one specialized endocrinology outpatient department Setting for screening and treatment along with dedicated nephrology ward with dialysis center. Family history of Type II Diabetes among first degree relatives, Addictions such as smoking, alcohol, Long duration of Diabetes mellitus (>10 years), Obese and overweight subjects (BMI>25), Poor compliance to the Physical exercise, Poor glycaemic control (HbA1C<8 mg/dl) were associated with a higher risk of Diabetic Nephropathy. Occurrence of Nephropathy among Diabetic subjects causes significant deterioration in quality of life as compared to subjects without Nephropathy in all of the different aspects of life such as Physical, psychological, social relationship and social environmental.

**Keywords:** diabetic retinopathy, non-communicable diseases, quality of life, International Diabetes Federation

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*\*Corresponding author*

## INTRODUCTION

Non-communicable diseases (NCDs) pose a significant threat to health and kill 41 million people annually, accounting for 71% of global deaths. Cardiovascular diseases are the most common, accounting for 17.9 million deaths annually. Cancers, respiratory diseases, and diabetes account for over 80% of premature NCD deaths [1]. Diabetes Mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbance of carbohydrates, fat and protein metabolism resulting from defect in insulin secretion, insulin action or both [2].

The International Diabetes Federation (IDF) published shocking figures in 2021, revealing that approximately 537 million adults (20-79 years) are living with diabetes, with the total number projected to rise to 643 million by 2030 and 783 million by 2045. The number of adults living with diabetes is projected to rise to 643 million by 2030 and 783 million by 2045 [3]. Asian Indians have a high predisposition to type 2 diabetes mellitus (T2DM), developing at a younger age and lower BMI than in western countries. They have a higher risk of coronary artery disease and microvascular complications compared to white individuals. The estimates in 2019 showed that 77 million individuals had diabetes in India, which is expected to rise to over 134 million by 2045 [4].

India faces a significant challenge in managing diabetic nephropathy, a condition affecting 1 out of 3 adults with diabetes [5]. With 2.2 lakh new patients diagnosed with End Stage Renal Disease (ESRD) each year, India faces a 3.4 crore dialysis demand. With 4950 dialysis centers, primarily in the private sector, the demand is less than half met with existing infrastructure. Families continue to struggle financially to afford the additional costs [6].

This study aims to screen diabetes and early renal disarrangement in diabetics to identify determinants of diabetic kidney disease and halt the progression of nephropathy. Currently, few studies focus on the progression of Type II diabetics to nephropathy in India, especially focusing on multiple determinants. The study aims to determine whether multiple causative factors in diabetics cause early renal derangement or individual factors contributing to nephropathy. Quality of life in diabetes and complications like nephropathy significantly impacts as the disease progresses. This study will help policymakers make recommendations for preventing diabetes and its complications, as well as implementing medical and non-medical interventions to improve quality of life.

### Aim

To study factors associated with development of diabetic nephropathy in Type II Diabetic patients and its effect on quality of life, in comparison to diabetic patients without diabetic nephropathy, in a tertiary care Hospital.

### Objectives

- To compare associated epidemiological factors among both the study groups (Nephropathy cases and Type II Diabetic controls) to find out the determinants of Diabetic Nephropathy.
- To assess and compare Health related quality of life (QOLOH) in patients having Type II Diabetes with and without Diabetic Nephropathy.

## MATERIALS AND METHODS

### Study Design

Case control Study

### Research Setting

The present study was conducted in 1400 bedded tertiary care hospital with medical colleges in a metropolitan city. This tertiary care hospital has six units in internal medicine department and one specialized endocrinology outpatient department Setting for screening and treatment along with dedicated nephrology ward with dialysis center.

There are about 6000 diabetic patients who get treated per month in endocrinology OPD. This tertiary care hospital treated 577 patients of diabetic nephropathy in 2020-2021, with a dedicated nephrology ward and dialysis center. The hospital is well-equipped with hematological investigations and a 10 hemodialysis machine, as well as an AKD ward.

### **Ethical Consideration**

Ethical clearance was obtained from Institutional Ethics Committee, which is guided by the ICH GCP guidelines, Ethical Principles outlined in the Declaration of Helsinki and the ethical guidelines on biomedical research on human participants laid down the Indian Council of Medical Research.

### **Confidentiality**

All the data collected as a part of this study was kept strictly confidential and used for the study only.

### **Sampling Unit**

#### **Cases: Definition of a case**

Patients with long standing history of diabetes plus retinopathy must be present on retinoscopy examination with the micro/macro albuminuria present in urinary albumin examination. Those cases identified as diabetic nephropathy by nephrologist were included in the study.

### **Eligibility criteria**

Diagnosed cases of diabetic nephropathy who were under treatment during the time period from the month of December 2019 up to May 2021 at the tertiary care hospital where the study was conducted and those who fulfilled inclusion criteria were considered as eligible for enrollment in the present study.

### **Sources of cases**

Cases were selected from the nephrology OPD of tertiary care Hospital in Metropolitan city.

### **Controls**

#### **Selection of controls**

Control will be selected day after selection of cases attending nephrology OPD having comparable age and sex who has type II Diabetes come for routine checkup in a Diabetic (Endocrinology) OPD in a tertiary care hospital.

### **Inclusion criteria**

*Cases:* Diagnosed diabetic nephropathy patients with Type II Diabetes attending nephrology OPD in tertiary care hospital during period of December 2019 – May 2021.

*Controls:* Type II diabetic patients of comparable age -Sex attending Diabetic OPD during the same study period

### **Exclusion criteria**

Nephropathy patients of aetiology other than Diabetes. Patients who are unwilling to participate.

### **Matching**

Controls were selected in such a way that they are comparable with case for age and sex.

## Sample size

$$\text{Sample size}(n) = r+1/r*\{(p)(1-p) (Z^{\beta} + Z / 2) (Z^{\beta} + Z\alpha/2)\} / (P1-P2)$$

n = Sample size in the case group

r= ratio of controls to cases

p = A measure of variability

$Z^{\beta}$  = Represents the desired power

$Z@$  = Represents the desired level of statistical significance (typically 1.96).

$P1-p2$  = Effect Size (the difference in proportions)

Odds ratio taken for Glycemic Control=2.71(7) to detect an odds ratio of 2.71 or greater an equal number of cases and controls ( $r=1$ ).

$P_{\text{case exp}} = 2.71 (0.79) / 0.79(2.71-1) + 1 = 0.91$

Average proportion Exposed =  $(0.91+0.79/2) = 0.85$

$n = 1+1 \{[(0.85) (1-0.85) (0.84+1.96)] / [(0.84+1.96) (0.91-0.79) (0.91-0.79)]\}$

$N = 138$

Therefore, minimum 138 cases and minimum 138 controls were included in the study, thus making the total sample size of 276 in the study. In this study cases to control ratio was taken as 1:1.

## Sampling Method

Every 4th OPD case of diabetic nephropathy was selected as a case by using systematic random sampling method. In similar way controls were selected from endocrinology OPD to avoid bias in the study method.

## Study Procedure

### Data Collection

After permission from concerned department approval from Institutional Ethics Committee was taken. An interview schedule was prepared according to the objectives of the study. Following data was collected by conducting face to face interview of both cases and controls. Data was collected from clinical records which includes systolic and diastolic blood pressure, fasting and post-prandial blood sugar levels, HbA1C for assessment of glycemic control over last three-month period. For assessment of renal function their Serum creatinine levels, Glomerular filtration rate (GFR) and Urine albumin level records were obtained. This information was recorded on Case Record Form as a part of data collection tool. Assessment of Health-related quality of life in both cases and controls was done using standard questionnaire (WHO-BREF).

### Data analysis and statistical methods

Along with data collection, the data were entered into an Excel sheet and Later data were imported to SPSS software, version 19 for analysis. The privacy and confidentiality of the study subjects have been strictly maintained. Analysis was done using SPSS software version 19 to find out odds ratio and P value to determine the association between different risk factors and occurrence of Nephropathy among diabetic patients. Chi-square analysis and Odds Ratio were used as a test of significance at 95% of Confidence interval.

## RESULTS

Diabetic Nephropathy in Type 2 Diabetic Patients with age- sex matched controls. The study was conducted at tertiary care hospital, from January 2020 to December 2021. The present study is based on observations of 276 study participants which included 138 cases and 138 controls. Cases were compared with age-sex matched controls (age +/- 5 years) in the ratio of 1:1.

**Table 1: Sociodemographic Characteristics of study Participants**

Characteristics	Cases (N=138)		Controls (N = 138)		P value
	n	%	n	%	
<b>Age in years</b>					
35-45	15	10.86	12	8.69	0.8220
46-56	41	29.71	35	25.36	
57-67	44	31.88	49	35.50	
68-78	37	26.81	40	28.98	
79-89	1	0.72	2	1.44	
<b>Gender</b>					
Male	81	58.69	81	58.69	
Female	57	41.30	57	41.30	
<b>Education</b>					
Illiterate	12	8.69	17	12.31	0.6532
Primary	14	10.14	20	14.49	
Secondary	29	21.01	25	18.11	
Higher Secondary	44	31.88	37	26.81	
Intermediate/diploma	17	12.31	14	10.14	
Graduate	22	15.94	25	18.11	
<b>Socioeconomic Status</b>					
Upper Middle	40	28.98	37	26.61	0.172
Lower Middle	37	26.81	45	33.03	
Upper Lower	49	35.50	52	37.68	
Lower	12	8.69	4	3.68	

The **table 1** shows the sociodemographic details of both cases and controls. The mean age of cases was 59.7years ± 10.63 years and that of controls being 60.79 years ±10.37 years. Matching for age was done with +/- 5 years. It was found that the maximum of cases 31.88% and controls 35.50% were in the age group 57-67 years of age. As seen in the above table 1 Matching was done for age and sex, for every case, a control of same gender was taken. 58.69% Male and 41.30% female were enrolled in both the study groups to make them comparable. Most of the study participants were attain higher secondary education, 31.88% and 26.81% amongst cases and controls respectively. Majority 35.50% of cases and 37.68% of controls fell in Upper Lower Class Whereas only 8.69% of cases and 3.68% of controls belonged to the lower class of the Modified Kuppaswamy Scale. There was no significant difference with respect to the gender, education, socioeconomic status between cases and controls (p=0.6532).

**Table 2: Comparison of Comorbidities amongst cases and controls**

Comorbidity	Cases (DN +group)	Controls (DN -group)	Odds Ratio	P value	95% CI
Hypertension	115(83.33%)	52(37.68%)	8.269	<0.0000001**	4.701- 14.55
CCF	12(8.69%)	4(2.89%)	3.19	0.01967*	1.003- 10.15
Diabetic Foot	9(6.52%)	5(3.62%)	1.852	0.1368	0.605-5.686
Dyslipidemia	89(64.49%)	62(44.92%)	2.226	0.0005474**	1.373-3.612
D. Neuropathy	27(19.56%)	37(26.81%)	0.664	0.07696	0.377-1.168
D.Retinopathy	131(94.92%)	19(13.7%)	117.2	<0.0000001**	47.59-288.7

Table 2 explains the percentage of different comorbidity distribution among cases and controls. Hypertension is the most frequent comorbidity among both cases (83.33%) and controls (37.68%), followed by dyslipidemia cases (64.49%), control (44.92%). 94.92% Nephropathic patients have Retinopathy. And 13.7% controls having complication of Retinopathy. There is strong association between Hypertension, Dyslipidemia and Diabetic Nephropathy in Type II Diabetic patients (P value <0.05%).

**Table 3: Factors associated with Diabetic Nephropathy**

Determining Factors of Diabetic Nephropathy		Cases (N = 138)		Controls (N = 138)		Odds Ratio (Confidence Interval)	P value
		n	%	n	%		
<b>Duration of Type II Diabetes Mellitus</b>	<b>&lt;10 years</b>	41	29.71	81	58.69	3.362 (2.04-5.532)	<b>&lt;0.001</b>
	<b>10 Years</b>	97	70.28	57	41.39		
<b>Addiction</b>	<b>Smoking</b>	56	40.57	36	26.08	1.935 (1.162-3.22)	<b>0.005328</b>
	<b>Alcohol</b>	29	21.01	18	13.04	1.77 (0.93-3.37)	<b>0.03908%</b>
<b>BMI</b>	<b>&gt;25</b>	113	81.88	61	44.20	5.631 (3.25-9.749)	<b>&lt; 0.0001</b>
	<b>18.5 -24.9</b>	25	18.11	76	55.07		
<b>Compliance To diet</b>	<b>Not compliant to diet</b>	41	29.71	87	63.04	0.2487 (0.15- 0.41)	<b>0.0001</b>
	<b>Compliant to diet</b>	97	70.28	51	36.95		
<b>Compliance to Physical Exercise</b>	<b>Not Compliant</b>	80	57.97	51	36.95	2.353 (1.45-3.816)	<b>0.0002364</b>
	<b>Compliant</b>	58	42.02	87	63.04		
<b>Glycemic control</b>	<b>Excellent</b>	7	5.07	12	8.69	2.697 (1.65-4.406)	<b>0.00002250</b>
	<b>Good</b>	12	8.69	39	28.26		
	<b>Less than ideal</b>	25	18.11	26	18.84		
	<b>Poor</b>	35	25.36	33	23.91		
	<b>Very Poor</b>	59	42.75	28	20.28		

The study found a significant association between long duration of Type II diabetes, smoking, alcohol, obesity, compliance to diet, noncompliance to physical activity, poor glycemic control, and nephropathy (p-value – <0.05). The majority of cases had over 10 years of diabetes history, suggesting a long-standing diabetes history as a risk factor for nephropathy. The odds of developing diabetic nephropathy among patients with diabetes more than 10 years is 3.362. Smoking addiction was found in 40.57% of cases and 26.08% of controls, while alcohol addiction was found in 21.01% of cases and 13.04% of controls. The odds of having nephropathy among smokers is 1.932, while alcohol addiction was found in 1.77 among nephropathy patients. Obesity was grouped into two groups: BMI >25-obese, overweight, and BMI <25. The odds of having nephropathy in higher BMI is 5.631. The majority of cases were compliant with diet, with an odds ratio of 0.2487, suggesting that diet compliance is a protective factor against nephropathy. Noncompliance to physical exercise was found in 57.17% of cases and 36.95% of controls, with an significant association between noncompliance to physical exercise and nephropathy (OR-2.353). The majority of cases (42.75%) had very poor glycemic control (Hba1C >8mg/dl), while the majority of controls (36.70%) had good glycemic control (28.26%). The odds of nephropathy in poor glycemic control patients is 2.697.

**Table 4: Comparison of Quality of life WHO BREF scale among cases and control**

Level of deterioration of quality of life:		Cases (n = 138)		Controls (n = 138)		Odds Ratio (Confidence Interval)	P value
		N	%	n	%		
<b>Physical health</b>	<b>Mild</b>	19	21.01	63	45.65	3.116 (1.62- 5.98)	0.000220
	<b>Moderate</b>	81	48.55	60	43.74		
	<b>Severe</b>	38	23.18	15	10.86		
<b>Psychological Health</b>	<b>Mild</b>	43	31.15	86	62.31	5.882 (2.50-13.83)	0.00001
	<b>Moderate</b>	62	44.92	45	32.60		
	<b>Severe</b>	33	23.91	07	5.07		
<b>Social relationship</b>	<b>Mild</b>	32	23.18	58	42.02	6.402 (2.864-14.31)	0.0001
	<b>Moderate</b>	67	48.50	72	52.17		
	<b>Severe</b>	39	28.26	8	5.79		
<b>Environment</b>	<b>Mild</b>	9	6.53	35	25.36	6.049 (3.162-11.57)	P <0.00001
	<b>Moderate</b>	73	52.89	99	71.73		
	<b>Severe</b>	56	40.57	14	10.14		

This table 4 shows a Comparison of deterioration of quality of life amongst cases and controls with respect to the Physical health, psychological health, social relationship, environmental domain.

The percentage of cases (23.18%) with severe deterioration in quality of life was more than twice that of controls (10.86%). There was a statistically significant difference ( $p < 0.001$ ) between cases and controls with respect to deranged quality of life. There was a strong association between physical health-related quality of life and nephropathy (OR-3.116). There was also a strong association between derangement in psychological health-related quality of life and diabetic nephropathy (OR-5.882). The percentage of cases (28.26%) with severe deterioration in quality of life was more than twice that of controls (5.79%). There was a strong association between severely deranged social relationship-related quality of life and nephropathy (OR-6.402). 40.57% cases had severe derangement in quality of life in the environmental domain, while 10.14% of controls had severe deterioration. The significant difference observed with respect to deranged quality of life among cases and controls, with OR -6.049 indicating that nephropathy might cause severe deterioration in quality of life.

## DISCUSSION

The present case-control study was conducted in a tertiary care hospital. Type II Diabetic with Nephropathy were selected as cases. Controls were Type II Diabetic having the same age (+/- 5 Years). Cases were compared with age-sex matched controls. The mean age of cases was 59.7 years  $\pm$  10.63 years and that of controls being 60.79 years  $\pm$  10.37 years which is similar to mean age as seen in study done by Tiwari A. et al [7]. and Hints S, Dube L, et al [8]. where it was 50.97+10.519 years and 52 Years  $\pm$  1.34 years. It was observed in the study the prevalence of CKD increases with age in the study subject.

Study reported as age increases, patients will be at greater probability of developing kidney diseases which are mostly reflected by proteinuria. Every one-year increment in age of diabetic patient, development of diabetic nephropathy increased by 3.7%; thereby increase in duration of 10 years of diabetic subject's increase in, the probability of developing diabetic nephropathy increases by 1.43 times. Many studies conclude that older age is a risk for developing diabetic nephropathy [9-11].

The study found that male nephropathy cases were more common than females, with 58.69% male and 41.30% female study subjects. The proportion of male subjects was higher, similar to findings from reports of U.S. Renal Data System and Centers for Disease Control [12], Ravindran R et al [13]. indicating that Male sex is a risk factor for diabetic nephropathy in type 2 diabetes subjects where as In contrast to the above findings, Unnikrishnan et al [14], Prasad B et al [15] study showed no such correlation exist between gender and diabetic nephropathy.

Educational status of the person could be a key determinant of disease occurrence and progression but in the present study (table 1) it was shown that no significant difference with respect to the education among cases and controls ( $p=0.6532$ ) and it corresponds with findings study done by Palo et.al [9], Hints S, Dube L, et al [8].

The present study (table 1) showed that the majority of patients of diabetic Nephropathy to the Upper Lower Class of Modified Kuppaswamy Scale. It was shown that socioeconomic strata had no impact on occurrence of diabetic nephropathy. Similar observation was reported by Palo et al [9]. and Hints S, Dube L, et al [8] that there is no effect of socioeconomic status on progression of nephropathy.

In this study about 67.39% of cases and 50.72% of controls had family history of Diabetic mellitus. There is a significant association between diabetic nephropathy and family History of Type II D.M.(OR-2.0076). In the Various studies Vijay et al [16], Hints S, Dube L et al [8], Kumar et al [17]. It was stated similar findings.

The present study (table no. 2) states that cases have higher proportions of Smokers and alcoholics than controls, in contrary other addictions (like paan, misri, Beetlenut, smokeless tobacco etc) are higher among controls than cases. There was strong association existing between Smoking, alcohol and Diabetic Nephropathy. The Odds of having Nephropathy among smokers and alcohol was 1.932 and 1.77 which reflects that smoking and alcohol might be the risk factors for nephropathy. Studies by Al-Rubeaan et al [18] and Unnikrishnan et al [14] also showed a significant association between smoking and nephropathy. However, Ravindran R et al [13] found no correlation between smoking and diabetic

nephropathy development, and found that smoking and alcohol consumption had a negligible impact on diabetes risk factors.

In the present study table 2 explain the percentage of different comorbidity distribution among cases and controls. Hypertension was the most frequent complication among cases (83.33%) and controls (36.68%), followed by dyslipidaemia cases (64.49%) and controls (44.92%). There is a strong association between nephropathy and hypertension in Type II diabetic patients ( $P$  value $<0.0001$ ). The odds of having hypertension among nephropathy cases are 8.269, suggesting hypertension may be a risk factor for nephropathy. Studies by Unnikrishnan et al [14] and Al-Rubeaan et al [18] also showed a significant association between hypertension and microalbuminuria, suggesting hypertension plays a major risk factor in the causation of nephropathy in diabetic subjects.

Dyslipidemia is a significant association between nephropathy and a deranged lipid profile, with an odds of having dyslipidemia among nephropathy cases being 2.226. This suggests that dyslipidemia may be a risk factor for nephropathy. Studies by Vinoth et al [19] and Dorit Ravid-Safran et al [20] found that patients with nephropathy had higher total cholesterol, low-density lipoprotein cholesterol, and triglycerides, and lower HDL values. However, Ravindran R et al [13] found that subjects with nephropathy had high prevalence of hypertriglyceridemia, high-LDL cholesterol levels, and low-HDL cholesterol levels in type 2 diabetes and diabetic nephropathy subgroups. However, no statistical significance was observed between dyslipidemia and diabetic nephropathy.

Diabetic Retinopathy is one of the most common complications of Diabetes and among the diagnosis criteria of Nephropathy. (Table no.2) and the findings are similar to study done by Ravindran R et al [13] at Chennai that Retinopathy patients had increased risk of developing nephropathy.

The present study (table no.11) show there is a significant association present between long duration of Type II Diabetes and Nephropathy. ( $p$ -value –  $<0.00001$ ). For calculation of OR, regrouping of data of Duration of Diabetes was done into 2 groups as follows, Duration of Type II Diabetes mellitus  $\geq 10$  and  $<10$  years. There is a significant association between long Duration of Type II Diabetes mellitus ( $>10$  years) and nephropathy as the Odds ratio is 3.362 suggesting Long Standing Diabetes history might be the risk factor for causation of Nephropathy among Diabetic subjects.

Similar finding seen in study done by Tiwari A. et al [7], Unnikrishnan et al [14] showed that duration of diabetes, statistically significant relationship with progression of Nephropathy in Diabetic subjects. Hints S, Dube L, et al [8] in his study show that every one-year increment in age of diabetic patient, development of diabetic nephropathy increased by 3.7%; that means for 10 years increase in duration of diabetes after diagnosis, the probability of developing diabetic nephropathy increases by 1.43 times (43%).

For find the association between obesity and nephropathy regrouping of data of obesity was done into 2 groups as, BMI  $>25$ -obese, overweight categories and BMI  $<25$ . There is a significant association between higher BMI and Diabetic Nephropathy. As odds of having higher BMI in nephropathy is 5.631 suggesting obesity might be the risk factors of diabetic nephropathy and the findings are identical to Hints S, Dube L, et al [8] where overweight is the independent factor in development of Nephropathy with odd ratio of 2.7 and  $p$  value $<0.001$ . Ravindran R et al [13], Ravid M et al [20] in their study also found that significant association between the development of nephropathy and BMI especially with overweight.

The present study found a significant association between diet compliance and nephropathy in diabetic patients. The odds of having diet compliance among cases and controls were 0.2487, suggesting that it is a protective factor against nephropathy. Ahmed et al [21]. found that inadequate diabetic diet knowledge is a positively related risk factor for diabetic nephropathy, with a  $p$  value of 0.003. Hints S, Dube L, et al [8] study also showed that non-adherence to a diabetic diet increases the risk of nephropathy changes in diabetic patients, with an odds ratio of 1.74 and a  $p$  value of 0.004.

The present study (table 3) shows that noncompliance to the physical exercise present among 57.97%% of cases and 36.95%% controls in the present study. There is a statistically significant difference ( $p <0.01$ ) between cases and controls with respect to physical inactivity and nephropathy with (OR – 2.353). suggesting noncompliance to physical exercise might be the Risk factor for the development of nephropathy. Study done by Ahmed et al [21] and Hints S, Dube L, et al [8] support above result by

showing non adherence to physical exercise is independent risk factor in occurrence of nephropathy in diabetic subjects with the odds ratio of 1.51 and 1.48.

The study reveals that a majority of cases (42.75%) have very poor glyceemic control (Hba1C >8mg/dl), while the majority of controls (36.70%) have good glyceemic control (28.26%). A statistically significant difference was observed between cases and controls with poor glyceemic control. The odds of having poor glyceemic control in nephropathy patients is 2.697, suggesting that poor glyceemic control may be a risk factor for nephropathy in diabetic subjects. Studies from by Unnikrishnan et al [14], Ravid et al [20] and Hintsas S, Dube L, et al [8] support this finding, showing a significant association between poor glyceemic control and the occurrence of nephropathy.

To determine the quality of life WHO –BREF HRQOL scale is implemented in this study. The BREF Scale measures various aspects of daily living, including physical health, psychological health, social relationship, and environmental health.

A significant difference was observed between cases and controls in physical health, psychological health, social relationship quality of life, and environmental quality of life, with Odds ratio of 3.116, 5.881, 6.402, 6.049 suggesting a strong association between nephropathy and deterioration in these domains. A study by Lauro et al [22] assessed the quality of life in diabetic nephropathy patients using a standardized HRQOL scale. The study found that patients experienced physical, psychosocial, medical interactions, and sexual relations deterioration, affecting their functional capacity for labor, recreational, and family activities.

A study by Kumar et al [17] found significant associations between HRQoL, D-39, and ADS scores in diabetic nephropathy patients. The study found that quality of life deteriorated with progression of diabetic nephropathy, with 41.7% females and 12.5% males experiencing poor quality of life.

## CONCLUSION

Family history of Type II Diabetes among first degree relatives, Addictions such as smoking, alcohol, long duration of Diabetes mellitus (>10 years), Obese and overweight subjects (BMI>25), Poor compliance to the Physical exercise, Poor glyceemic control (HbA1C<8 mg/dl) were associated with a higher risk of Diabetic Nephropathy. Occurrence of Nephropathy among Diabetic subjects causes significant deterioration in quality of life as compared to subjects without Nephropathy in all of the different aspects of life such as physical, psychological, social relationship and social environmental.

## Recommendations

Diabetes and complications, like nephropathy, are linked to various factors and interplays. Early detection is crucial, especially among at-risk populations with a diabetes family history. Health education and lifestyle measures are effective in preventing complications. Public health centers should provide screening facilities, counselling sessions, deaddiction activities, and regular monitoring to assess disease progression, medication compliance, and comorbidities. Known diabetic patients should be aware of early signs of renal derangement and use quality of life assessment tools to detect psychosocial, socio-environmental, and economic issues related to disease occurrence and treatment.

## Limitations of Study

The current study was conducted in a tertiary care hospital of a metropolitan city; hence the results cannot be extrapolated to the entire population.

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