Section: General Medicine

Original Research Article

A PROSPECTIVE STUDY ON RENAL FUNCTIONS OF TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL AND ITS BIOCHEMICAL CORRELATES

Suman Kumar Panda[1], Gargi Rawat[2], Ankit Anand[3], Ashok Sunder[4], Ashim Mishra[5]

[1]Associate Professor, Manipal Tata Medical College, Manipal Academy of Higher Education, Manipal, India.
[2]DNB Trainee, General Medicine, Tata Main Hospital, Jamshedpur, Jharkhand, India.
[3]Assistant Professor, Manipal Tata Medical College, Manipal Academy of Higher Education, Manipal, India.
[4]Head Consultant, General Medicine, Tata Main Hospital, Jamshedpur, Jharkhand, India.
[5]Professor & Head, Forensic Medicine, Manipal Tata Medical College, Manipal Academy of Higher Education, Manipal, India

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Corresponding Author:
Dr. Ashim Mishra,
Email: ashim.mishra.forensic@gmail.com

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Abstract

Background: This prospective study was undertaken with the objective to analyse the biochemical profile of Type 2 diabetes mellitus patients of more than 5 years duration and to evaluate the variation in Glycemic control (HbA1C) with UACR and eGFR which marked the extent of renal impairment. **Methodology:** Based on the inclusion and exclusion criteria, the participants were included in the study. The demographic correlates, anthropometric parameters were obtained before the study. The blood and urine samples collected at start of study, at 3 months and 6 months were sent to laboratory for estimating Glycosylated Haemoglobin, Urinary Albumin-to-Creatinine Ratio and the estimated Glomerular Filtration Rate. **Results:** 39% of the participants belonged to the age range of 55-64 in a male-to-female ratio of 1.94:1. The mean duration of diabetes among participants was 90.13 months, with a standard deviation of 27.02. Approximately 27% of individuals possess a BMI (Body Mass Index) within the normal range of 18.5-24.9 while 21% of the population have a morbidly obese body mass index (BMI) more than 35. Significant differences in HbA1c, UACR, serum creatinine, and eGFR were observed between patients with and without complications at 0, 3, and 6 months. There was a significant positive correlation between HbA1c and UACR, which strengthens over time. A significant negative correlation was observed between HbA1c and eGFR, which decreases over time. A weak, non-significant negative correlation was observed between UACR and eGFR. A significant positive correlation was found between the duration of diabetes and HbA1c. There was a significant negative correlation between the duration of diabetes and eGFR initially, which weakens over time. C**onclusion:** The findings emphasized the critical need for comprehensive diabetes management to reduce the burden of microvascular and macrovascular complications.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) stands as a paramount global health challenge, reflecting the intertwining influences of modern lifestyles, urbanization, and genetic predispositions.

Glycosylated Haemoglobin (HbA1c) is both a diagnostic and therapeutic marker in diabetes management, with levels ≥6.5% diagnostic of diabetes and lower levels targeted in treatment to reduce the risk of complications.[1]

Landmark studies such as the Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) have shown that intensive glycemic control, evidenced by lower HbA1c levels, significantly reduces the risk of microvascular complications.[2]

Hence, HbA1c remains central to diabetes management, guiding therapeutic decisions and monitoring disease progression.

Diabetic nephropathy is one of the most serious microvascular complications of T2DM, potentially leading to end-stage renal disease (ESRD). The

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urinary albumin-to-creatinine ratio (UACR) is a crucial marker for assessing kidney function in diabetic patients. UACR measures the amount of albumin excreted in the urine relative to creatinine and serves as an early indicator of kidney damage.[3] Microalbuminuria (UACR 30-300 mg/g) is often the first sign of diabetic nephropathy, signifying increased glomerular permeability. Macroalbuminuria (UACR >300 mg/g) indicates more advanced kidney damage and a higher risk of progression to ESRD. Regular monitoring of UACR in T2DM patients is essential for early detection and intervention, potentially slowing the progression of kidney disease through optimized glycemic control, blood pressure management, and the use of renin-angiotensin-aldosterone system inhibitors.[4]

The interrelationship between HbA1c, UACR, and eGFR in Diabetic patients is complex and major alterations induce the progression of diabetic nephropathy.

In T2DM patients, a declining eGFR often accompanies increasing UACR, reflecting progressive nephropathy. Monitoring eGFR allows clinicians to stage CKD, guide treatment decisions, and assess the risk of complications. Early detection of decreased eGFR can prompt interventions to preserve kidney function, such as tighter glycemic control, blood pressure management, and lifestyle modifications.[5]

This prospective study was undertaken with the objective to analyse the biochemical profile of Type 2 diabetes mellitus patients of more than 5 years duration and to evaluate the variation in Glycemic control (HbA1C) with markers of renal impairment i.e microalbuminuria (UACR) and eGFR.

MATERIALS AND METHODS

This study was conducted at the Department of General Medicine after Ethical approval by the Hospital Ethics committee vide TMH/IEC/June/035/22 during the period 1st July 2022 to 31st Dec 2023.

The patients visiting the outpatient department of General Medicine formed the population of the study and was prospective observational in design.

Inclusion Criteria

All patients with diagnosed Type 2 Diabetes mellitus of age group of more than 35 years and less than 75 years.

Exclusion Criteria

1. The patients having history of Tuberculosis, HIV, malignancy and connective tissue disorders were excluded from the study.
2. The patients having diagnosed Type-1 DM were also excluded from the study.
3. Pregnant females were also excluded from the study.

Based on the inclusion and exclusion criteria, the participants were included in the study after obtaining informed written consent and complete anonymity of the identity was maintained throughout the study.

The data collection sheet comprised of three parts.

Part-1 contained the demographic correlates like age, sex, duration of diabetes, history of smoking and consumption of alcohol were recorded. Part-2 comprised of the anthropometric parameters which included weight (kg), waist circumference(cm), hip circumference (cm) and height (cm) as primary variables which Basal Metabolic index and waist hip ratio were calculated.

The Blood samples collected at start of study, and during repeat visit at 3 months and 6 months were sent to laboratory for estimating Glycosylated Haemoglobin (HbA1C) to determine average blood glucose levels over the past 3 months and for estimating Serum Creatinine to assess kidney function.

The Urinary Albumin-to-Creatinine Ratio (UACR) was calculated from the albumin and creatinine levels obtained from lab after analysis of urine samples and the estimated Glomerular Filtration Rate (eGFR) was also calculated.

Statistical Analysis: The total samples required for the study was 90, based where Z1-α/2, Value of the standard normal deviate at 95% level of confidence interval was 1.96, Z1-β Value of standard normal deviate at 80% power of the study was 0.84, r (Correlation of renal parameters) was 0.079 and C (Fisher Z transformation of the minimum correlation coefficient) was 0.079.

Based on inclusion and exclusion criteria, a total of 114 cases were included in the study where 14 participants failed to report during follow up visit during 3rd and 6th months for which they were excluded from the study. Thus, a total of 100 cases were included in the study.

The data were entered in Microsoft excel and analysis done by SPSS Version 22.0 where frequencies and proportions were used for categorical data representation and correlation of qualitative data were done by Pearson correlation test, independent t-test and one-way ANOVA. Mean and standard deviation were used to represent continuous data.

RESULTS

The mean age in the study population is 56.88 ±10.798 years, most of the patients (39%) belong to the age group of 55-64 years with male to female ratio of 1.94: 1. [Table 1]

The anthropometric measurements of the study population revealed mean height and weight of 158.25 ± 10.48 cm and of 68.27 ± 18.46 kg respectively. The Basal Metabolic Index calculated from the primary data had a mean of 19.213 ± 3.22 kg/m². The waist circumferences ranged from 63.00 cm to 91.00 cm, with a mean of 74.81 ± 5.51 cm and the hip circumferences ranged from 65.00 cm to 92.00 cm, with a mean of 78.99 ± 5.49 cm.

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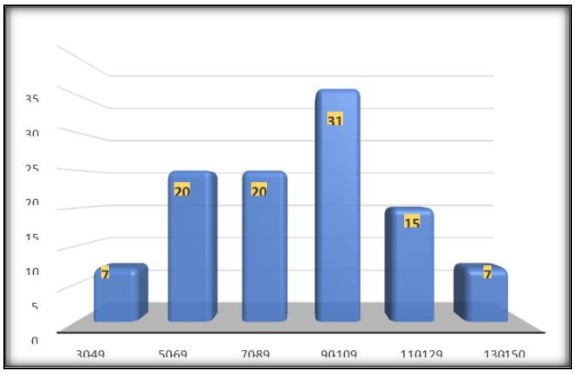

Figure 1: Duration of Diabetes in study population

The mean duration of diabetes was found to be 90.13 ± 27.02 months. Most of the patients (31%) had duration between 90-110 months. [Figure 1]

At 0 months, the Pearson correlation coefficient was 0.294, with a significance level of p = 0.003, indicated a modest but statistically significant correlation. This correlation strengthened over time, with Pearson correlation of 0.393 at 3 months and 0.438 at 6 months respectively. The progressively strong significant correlation between HbA1c and UACR, highlighted role of these biomarker in monitoring. [Table 2].

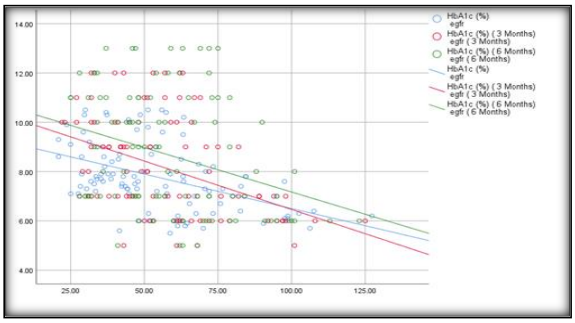

Figure 2: Correlation of HBA1C with e-GFR.

The correlations between HbA1c and eGFR at three different time point at 0 month, 3 months were -0.463, -0.419 and -0.317 respectively indicated a negative association. The significance levels were consistently below 0.01 pointed that these correlations were statistically significant at the 0.01 level. [Figure 2]

The correlations between UACR and eGFR at 0 months, 3 months, and 6 months were -0.048, -0.058 and -0.013 respectively indicated a negligible and non-significant association and were not statistically significant at the 0.01 level.

The findings revealed significant positive correlations between the duration of diabetes and HbA1c levels at various time points which was 0.314 , 0.371 and 0.383 at 0 month, 3 months and at 6 months interval with P<0.001. [Table 3]

The findings pointed significant negative correlations between the duration of diabetes and eGFR at various time points. Specifically, the Pearson correlation coefficient between the duration of diabetes and baseline eGFR was -.243, with a significance level of .015, indicating a statistically significant inverse correlation. This correlation slightly decreased over time, with eGFR at 3 months showing a correlation of -.198 (p = .048). The correlation between the duration of diabetes and eGFR at 6 months was not statistically significant. These findings suggest that a longer duration of diabetes was significantly associated with lower eGFR levels, particularly at baseline and after 3 months, highlighting the potential impact of prolonged diabetes on renal function.

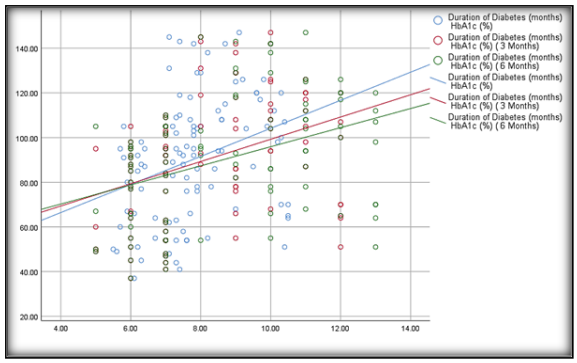

Figure 3: Correlations of eGFR and duration of diabetes

The study's analysis revealed significant negative correlations between the duration of diabetes and eGFR at various time points. Specifically, the Pearson correlation coefficient between the duration of diabetes and baseline eGFR was -.243, with a significance level of .015, indicating a statistically significant inverse correlation. This correlation slightly decreased over time, with eGFR at 3 months showing a correlation of -.198 (p = .048). The correlation between the duration of diabetes and eGFR at 6 months was not statistically significant. These findings suggest that a longer duration of diabetes is significantly associated with lower eGFR levels, particularly at baseline and after 3 months, highlighting the potential impact of prolonged diabetes on renal function.

Among the patients surveyed, 29% reported smoking, while 16% indicated a history of alcohol consumption.

The significance levels indicate that smoking had a statistically significant effect on HbA1c at baseline and 6 months, while its effects on UACR and eGFR were not significant. In contrast, the impact of alcoholism on these metrics did not reach statistical significance at any time point.

Table 1: Age and Sex Preponderance in study population.

Age Group (Years)	Male	Female	Total number
35-44	13	4	17
45-54	14	7	21

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55-64	15	14	39
65-74	14	9	23
Total	66	34	100

Table 2: Correlation of HbA1c and Urine Albumin Creatinine Ratio

Correlations	0 month	3 months	6 months
Pearson Correlation	.294	.393	.438
Sig. (2-tailed)	0.003	0.001	0.001
N	100	100	100
**. Correlation is significant at the 0.01 level (2-tailed).			

Table 3: Correlations of Hba1c and duration of diabetes

Correlations					
		Duration of Diabetes	HbA1c (%) (0month)	HbA1c (%) (3 months)	HbA1c (%) (6 months)
Duration of Diabetes (months)	Pearson Correlation	1	.314**	.371**	.383**
	Sig. (2-tailed)		.001	.000	.000
	N	100	100	100	100

Table 4: Student t test for association Smoking & Alcoholism with test factors

		HbA1c	UACR	eGFR	HbA1c (3 m)	UACR (3 m)	eGFR (3 m)	HbA1c % (6m)	UACR (6m)	eGFR (6m)
Smoking	t	2.26	0.43	-0.59	2.59	0.41	-0.50	2.44	0.43	-0.15
	Sig. (2tailed)	0.03	0.67	0.56	0.01	0.69	0.62	0.02	0.67	0.88
Alcoholism	t	1.43	1.20	0.31	1.54	1.40	0.70	1.31	1.46	1.02
	Sig. (2tailed)	0.16	0.23	0.75	0.13	0.16	0.49	0.19	0.15	0.31

DISCUSSION

The mean age and sex pre in the study was similar to study done at Puducherry with mean age was 54.25±6.92 and 68% were male participants while it was comparable to study at Taiwan where average age at baseline was 63.2 ± 12.7 years.[6,7]

The mean duration of diabetes in the present study was comparable to other studies where the mean ranged from 8.06 ± 5.66 years to 11.3 years stress on importance of regular monitoring and follow up of patients who present with microalbuminuria and prevent further deterioration.[8,9]

The longer duration of diabetes was significantly associated with higher HbA1c levels, emphasizing the progressive nature of glycemic control deterioration over time in diabetic patient similar to studies done at India.[10]

The Basal Metabolic Index in our study was similar to studies done in India owing life style and food habits have a detrimental effect influenced geographical location.[6]

This present study reaffirm the fact smoking impacted HbA1C level but limited influence on on UACR and eGFR substantiate the fact the increase of glycemia due to mobilization of catecholamines and cortisol production which had been proved in earlier studies.[11]

In contrast to general notion, consumption of alcohol had no statistical significance at any time point which contrasted study done by Steiner et al which pointed towards contribution of alcohol intake to the development or exacerbation of type 2 diabetes.[12]

The findings in our study pointed a progressively stronger significant correlation between HbA1c and UACR over the study period, highlighting the importance of these biomarkers in monitoring the study population similar to other studies in India.[13]

The findings restated the fact that the longer duration of diabetes was significantly associated with higher HbA1c levels, emphasizing the progressive nature of glycemic control deterioration over time in diabetic patient similar to other studies in India.[14,15]

A significant negative correlation existed between the duration of diabetes and eGFR at various time points highlight the potential impact of prolonged diabetes on renal function.

CONCLUSION

The findings were consistent with previous authors emphasized the critical need for comprehensive diabetes management to reduce the burden of microvascular and macrovascular complications. Further multi centric studies with larger sample sizes and longitudinal study designs are warranted to confirm these associations and develop targeted interventions for preventing complications in diabetic patients.

Limitation: The study was confined to one geographical area and follow up was done for maximum 6 months were major limitations of the study.

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