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Original Research Article

Study of Cystatine C-As Innovative Biomarker for Early Renal Improvement in Diabetic Patients

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Conflict of interest: Nil

Abstract

Background: Due to insidious onset and slow development of CKD lead to diabetic nephropathy (DN). The parameters to diagnose CKD and DN are microalbumin and GFR, these pathophysiological conditions. Hence, cystatin C, which is clearly excreted from the kidney in the circulatory system. Hence, cystatin C is an ideal method to diagnose CKD and DN.

Method: Out of 60 type-2 DM patients, 30 were diagnosed with diabetic nephropathy, and 30 diabetics were without nephropathy. The parameters of both groups were compared with 30 healthy (controlled) groups, and significant results were noted.

Results: Blood pressure, blood glucose, HbA1c, urea, Serum cr, microalbuminuria, and cystatin-C had significant p-values ($p < 0.001$).

Conclusion: Serum cystatin-C has excellent diagnostic value in early diagnosis of CKD and diabetic nephropathy.

Keywords: Diabetic, Nephropathy, Chronic Kidney disease, HbSA1C, Cystatin-C, eGFR.

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Introduction

Chronic kidney disease (CKD) is one of the worldwide health problems with an increasing incidence, prevalence and expensive treatment. Diabetic nephropathy (DN) is one of the most common serious complications of diabetes.

DN refers to kidney damage (caused by chronic hyperglycemia, which becomes the leading cause of end-stage renal disease (ESRD) instead of glomerulonephritis-related chronic kidney disease (CKD). Due to its insidious onset and slow development, the entire course of the disease could be irreversible at diagnosis, which leads to disability and death eventually [1]. Therefore, the early diagnosis of DN is of significant importance for its treatment and prognosis.

At present two main clinical indicators, including urine albumin and estimated glomerular filtration rate (eGFR), are used to diagnose DN. However, albuminuria has the same deficiencies. Albumin is not a unique marker of diabetic kidney damage [2]. Urine microalbumin is likely to be affected by menstrual periods, urine retention, blood pressure, exercise, and urinary tract infections. eGFR is mainly estimated by the serum creatinine concentration, which is likely to be affected by muscle content, gender, age, diet, and medication [3]. Cystatin C (Cys-C) is a non-glycosylated low molecular weight (I3 KDa) protein whose concentration is closely related to GFR. It stably exists in all nucleated cells in the human body. The kidney is the only organ that clears cys-C from the circulatory system, and the GFR mainly determines the concentration of serum cys-C [4]. Hence, an attempt is made to study the serum cystatin C along with the related parameters of CKD and DN.

Material and Method

60 (sixty) adult type-2 diabetic patients regularly visited the PSP Medical College Hospital and Research Institute, Tambaram, Panruti, Tamil Nadu 631604, and were studied.

Inclusion Criteria: Patients clinically diagnosed with type-2 DM, above 18 years. The patents who gave their consent for study in writing were selected. Moreover, 30 (thirty) healthy adults were included as a control group.

Exclusion Criteria: Patients with chronic liver disease, cardiovascular patient's malignancy, hypertension, and immunocompromised patients were excluded.

Method: Out of 60 patients of type-2 DM. 30 patients of type-2 DM, 30 patients without nephropathy, 30 patients with type- DM with nephropathy, and 30 healthy adults as a control group were compared. Anthropometric parameters such as BMI (body mass index). Blood pressure was measured by a sphygmomanometer. Blood examinations such as fasting, PP, random blood glucose, blood urea, serum creatinine, total protein, uric acid, and serum albumin were analyzed using the Vitros 5:1 FS dry chemistry autoanalyzer based on the principle of reflectance photometry from orthoclinical diagnosis (OCD). Glycated hemoglobin (HbA1c) was measured by the HPLC (high-performance liquid chromatography) method on the Bio-Rad D-10 automatic glycated hemoglobin analyzer. Urinary albumin was measured by a quantitative immunoturbidimetric method on a 5.1 FS dry chemistry autoanalyzer. Cystatin C levels were determined using Agappe MISPA-iZ based on nephelometric methodology. The GFR calculation was made using the CKD-EPI (chronic kidney disease epidemiology collaboration 2012) equation.

The duration of study was from March 2025 to February 2026.

Statistical Analysis: Anthropometric and biochemical parameters of three groups were compared using the ANOVA test; Pearson's correlation coefficient (R) was used wherever applicable, and significant results were noted. The statistical analysis was carried out SPSS software. The ratio of males and females was 2:1.

Observation and Results

Table 1: Comparison of anthropometric and Biochemical parameters

- BMI (Kg/m_2): 24.4 (±3.85) in controlled group, 24.6 (±4.20) in type-2 DM without nephropathy, 24.55 (±4.46) in type-2 DM patients with nephropathy, F value 0.019 and p>0.98 (p value is insignificant).
- SBP (mmHg), DBP (mmHg): Duration of diabetic (year), FBS, PPBS, HbsA1C, Urea (mg/dl), serum (reatinine (mg/dl) Uric acid, total protein (gm/dl) cystatin C (mg/L), GFR (m/min) Micro albumin urea (mg/L) were compared in controlled group type-2 DM without nephropathy, type-2 DM patients with nephropathy and p value is highly significant (p<0.001).

Table 2: Correlative study of cystatin C and Micro albumin with anthropometric and Biochemical indices in type-2 DM patients and II DM with nephropathy patients

- Diabetic duration, Urea, Serum Creatinine, Albumin, GFR have significant p value (p<0.001).

Table 1: Comparison of anthropometric and Biochemical parameters

Parameters	Group-I Healthy (controls) (30)	Group-II type-II DM without Nephropathy (30)	Group-III type-II DM with Nephropathy (30)	F value	P value
BMI	24.4 (±3.85)	24.6 (±4.20)	24.55 (±4.46)	0.019	p>0.98
SBP (mmHg)	121.2 (±5.4)	125.6 (±12.9)	131.94 (±17.2)	5.339	P<0.001
DBP (mmHg)	79 (±3.5)	80.3 (±6.53)	83.15 (±10.6)	2.47	p>0.09
Duration of diabetic (year)	--	6.52 (±5.65)	8.96 (±8.11)	--	P<0.001
FBS (mg/dl)	97.4 (±5.5)	210.75 (±40.34)	153.36 (±30.08)	112	P<0.001
PPBS (mg/dl)	108.4 (±18.4)	275.8 (±45.82)	248.32 (±38.28)	185.8	P<0.001
HbsA1C	5.52 (±0.4)	10.86 (±2.52)	8.8 (±2.34)	54.4	P<0.001
Urea Mg/dl	19.76 (±4.92)	26.05 (±10.8)	113.16 (±25.8)	304.1	P<0.001
Serum creatinine (mg/dl)	0.72 (±0.16)	0.7 (±0.37)	4.80 (±2.36)	88.2	P<0.001
Uric Acid	4.85 (±1.36)	4.4 (±1.68)	7.78 (±2.12)	33.07	P<0.001
Total protein (gm/dl)	7.22 (±0.42)	6.73 (±0.6)	5.84 (±0.88)	33.6	P<0.001
Albumin (gm/dl)	4.08 (±0.26)	3.55 (±0.50)	2.7 (±0.46)	82.4	P<0.001
Cystatin C mg/dl)	0.81 (±0.14)	0.98 (±0.24)	2.44 (±0.58)	174.7	P<0.001
eGFR (ml/dl)	102.5 (±18.5)	83.74 (±22.4)	25.16 (±8.30)	160.4	P<0.001
Micro Albumin uria (mg/L)	11.14 (±8.8)	64.4 (±10.2)	700.8 (±58.8)	3630.02	P<0.001

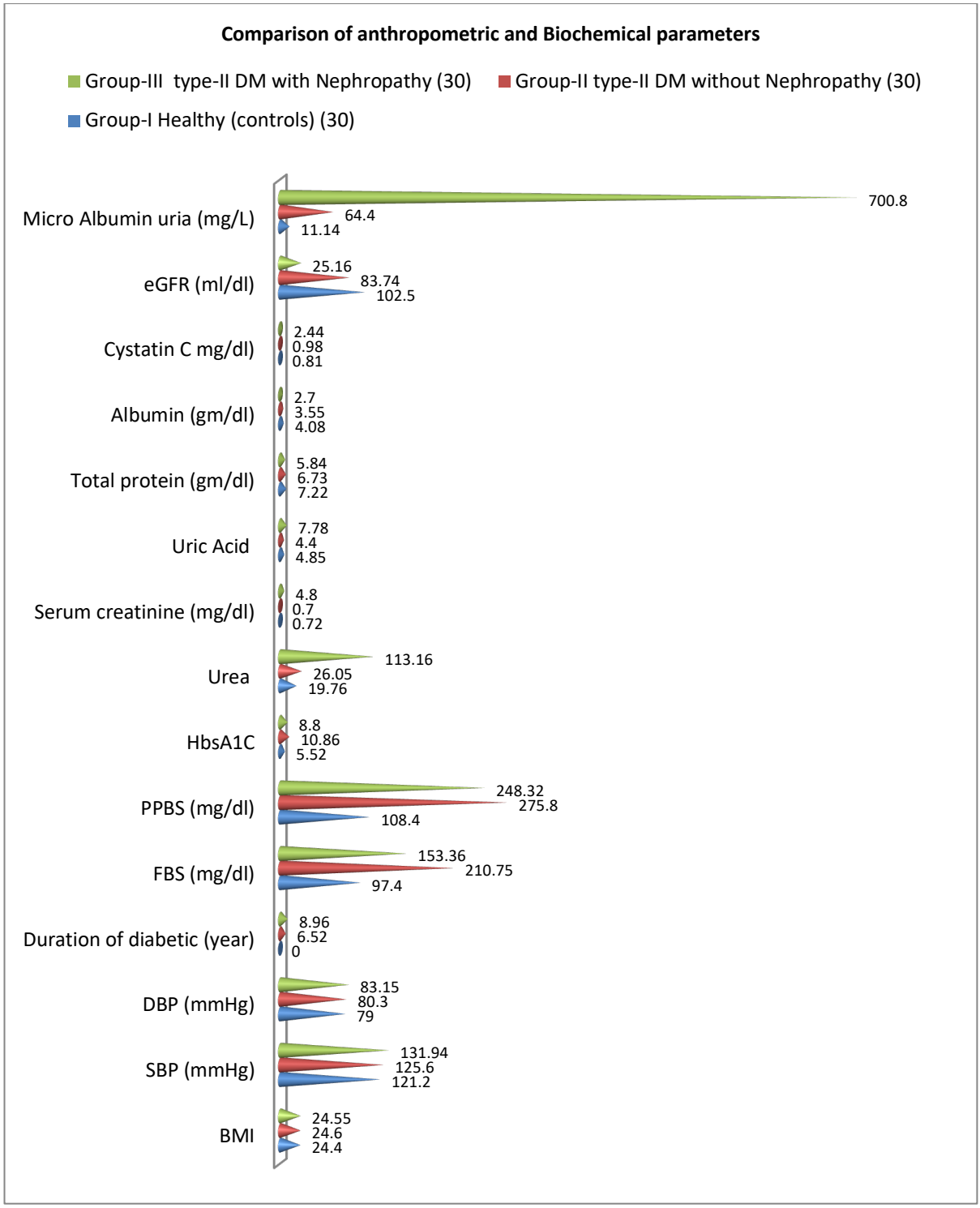

Figure 1: Comparison of anthropometric and Biochemical parameters

Table 2: Correlation of cystin C and Micro albumin with Anthropometric and Biochemical indices in type-II DM with and without Nepthropathy

Parameters	r value		Micro albumin	
Diabetic duration	0.187	0.036 *	0.183	0.042 *
Urea	0.806	0.001 *	0.502	0.0001 *
Serum creatinine	0.864	0.001	0.611	0.0001 *
GFR	0.901	0.001	0.564	0.001 *
Albumin	0.473	0.001	0.362	0.001 *

*** = p value is highly significant (p<0.001)**

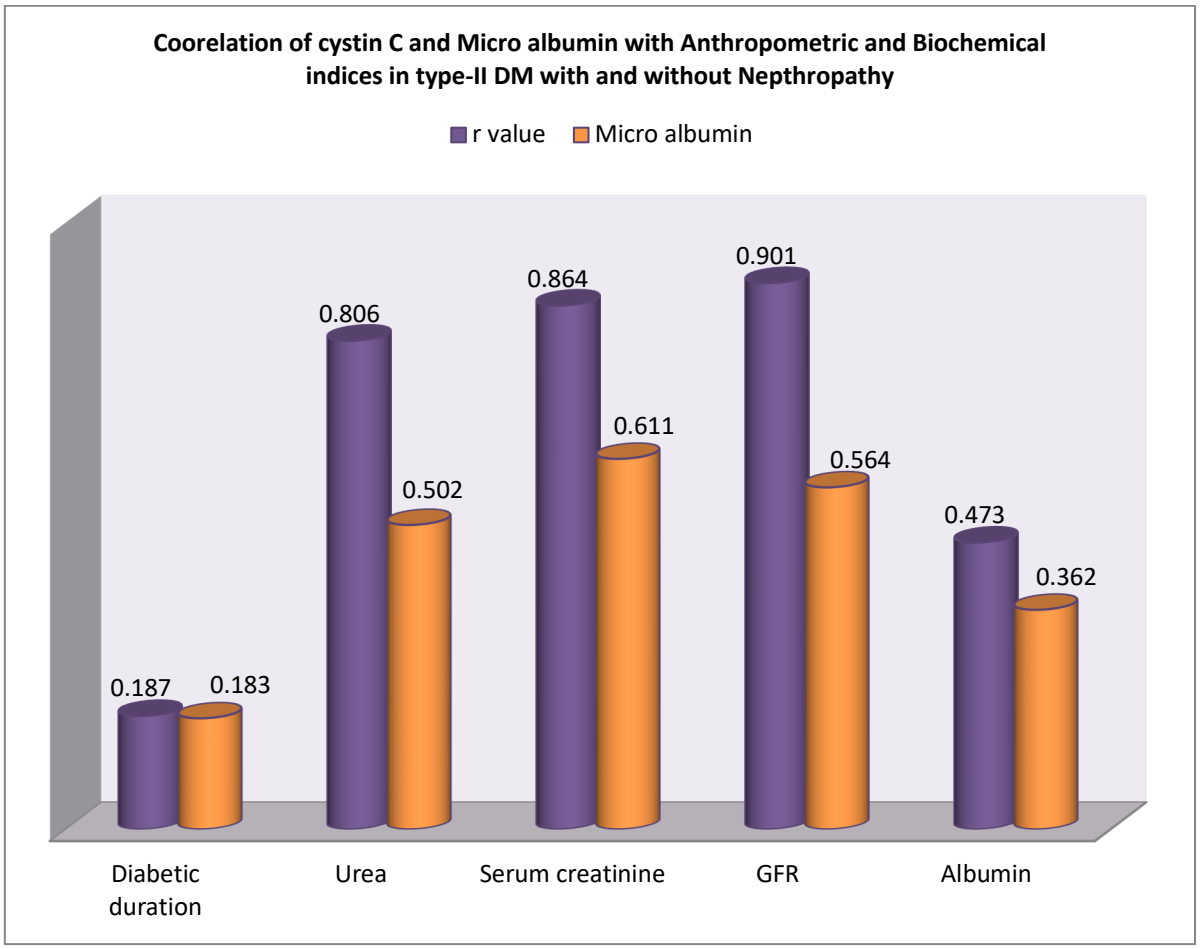

Figure 2: Coorelation of cystin C and Micro albumin with Anthropometric and Biochemical indices in type-II DM with and without Nepthropathy

Discussion

Present study of cystatin-C as an innovative biomarker for early renal improvement in diabetes mellitus patients. The various parameters related to diagnosing chronic kidney disease (KD) and diabetic nephropathy (DN) are blood pressure, blood glucose, HbA1c, urea, serum creatinine, uric acid, total protein, albumin, eGFR, microalbumin, and cystatin-C, which has a significant p value ($p < 0.001$) (table 1). Correlation of cystatin C and microalbumin biochemical parameters of type-2 DM and DN had a significant p value ($p < 0.001$) (Table 2). These findings are more or less in agreement with previous studies [5,6,7].

The early detection of impairing renal function at the primary stage is often identified using the diagnostic tool cystatin-C, which may delay and reduce the complications, thereby improving the standard or quality of life [8]. The main diagnostics of CKD are microalbuminuria and eGFR, but recently cystatin-C is used because it is the most accurate endogenous marker of GFR (surpassing creatinine). Cystatin-C is not influenced by nutritional status, inflammatory process, or neoplastic state with age or muscle mass. The cystatin-C (cys-C) levels are related to detect impairment in tubular function in early stages and are effective biomarkers in CKD and DN [9].

After globular filtration cys-C is completely catabolized in proximal tubules not returned back into blood circulation, only a small amount of cys-C is excreted in urine. Cys-C is being considered as a promising substitution of serum creatinine, as it appears to be less influenced by factors known to confound creatinine concentrations, such as muscle build and portion intake [10].

It is also revealed that Cys-C levels are a possible indicator of the development of DN in people with type-2 DM and that values rise as the condition worsens. This finding supports earlier research and provides more proof that serum cys-C can be used as an early indicator in clinical settings and can distinguish between different levels of kidney impairment [11].

Summary and Conclusion

It is concluded that serum cystatin-C (cys-C) is a significant biomarker of diabetic nephropathy (DN)

among patients with type-2 DM. Serum cys-C levels are significantly closer to an accurate measurement of eGFR and are significantly more sensitive to detect early GFR impairment. It can also positively monitor kidney function progression and predict adverse outcomes among type-2 DM patients. In day-to-day clinical practice, serum cys-C is not a routinely done test, as it is a very expensive and not widely available assay, though it is one of the earliest markers of DN. It is suggested that serum cys-c could be used in the future for grading or staging CKD in DN in type-2 DM patients because serum cys-c levels rise with the stage of renal dysfunction. However, more prospective multicentric studies with a large number of patients can validate these results.

Limitation of study: Owing to remote location of research centre, small number of patients, lack of latest techniques, we have limited findings and results.

This research work was approved by the ethical committee of PSP Medical College hospital and research institute Tambaram, Panruti, Tamil Nadu-631604.

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