A Cross Sectional Study of Prevelance of Ckd in Adults with Type 2 Diabetes

Dr.Panuganti Ratnachary¹, Dr.K.Sudha Rani^{2*}, Dr.Panuganti Raveen³

¹Assistant Professor, Kamineni Academy of Medical Sciences and Research Centre, LB Nagar, Hyderabad. 2* Professor and HOD, Department of Anatomy, Kakatiya Medical College, Warangal. ³ MBBS.

Corresponding Author: Dr.K.Sudha Rani

Abstract

Introduction: Diabetes mellitus is a major cause of concern because of its increasing prevalence rate globally. The increase in burden is highest in the Asian and African countries.[1] As per estimates, in year 2013, worldwide, 382 million people aged 20–79 years were living with diabetes, 46% of them being undiagnosed. Materials and methods: This observational, multi-center, cross-sectional study was conducted in the department of General Medicine, Kamineni Academy of Medical Sciences and Research Centre, Hyderabad from January 2017 to December 2018. The primary objective of the START India study was to estimate the proportion of T2DM patients with CKD (GFR <60 ml/min/1.73 m² or albumin creatinine ratio [ACR] \geq 30 mg/g or \geq 3 mg/mmol or both) as defined by Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines. ACR was calculated from urine creatinine and albumin, while GFR was estimated by using modification of diet in

renal disease equation:

Results: Mean duration of T2DM was 102 months. Summary of the incidence and history of diabetes-induced complications is presented in Table 2. Almost 44% of the study population was reported dyslipidemia and hypertension each, whereas the low percentage of patients had microvascular and macrovascular complications. This analysis revealed that 697 (46.47%) of the T2DM patients had CKD (Urinary ACR [UACR] \geq 30 mg/g and/or estimated GFR (eGFR)<60 mL/min/1.73 m2). Renal dysfunction was found as per eGFR criteria (<60 mL/min/1.73 m2) and UACR criteria (\geq 30 mg/g) in 22.60% and 34.5% of study population respectively.

Conclusion: CKD is highly prevalent among patients with T2DM in India. Several risk factors for CKD are well elucidated and amenable to interventions. Our data suggest substantial unmet challenges of CKD risk factors among T2DM population. Therefore, routine screening for renal impairment and enhanced programme for global risk factors reduction is important to stem the tide of CKD in T2DM. **Key words:** CKD, T2DM, GFR,ACR.

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I. Introduction

Diabetes mellitus is a major cause of concern because of its increasing prevalence rate globally. The increase in burden is highest in the Asian and African countries.¹ As per estimates, in year 2013, worldwide, 382 million people aged 20–79 years were living with diabetes, 46% of them being undiagnosed. This number is expected to increase to 592 million by the year 2035. India plays host to a 65.1 million patients with diabetes, second only to China as per estimates in International Diabetes Federation Atlas 2013.² Furthermore, the average age at which Asian Indian develops diabetes is now estimated to be about 10 years lower than that of their western counterparts.

Increase in prevalence of type 2 diabetes mellitus (T2DM) is associated with a consequent increase in the incidence of related microvascular as well as macrovascular complications, including kidney disease.³ Diabetes has been found to be the primary cause of kidney failure in nearly 45% of patients undergoing dialysis.⁴ Diabetic nephropathy is one of the common microvascular complications of T2DM. Data from the US population suggests that nearly 15–23% of diabetic patients suffer from moderate to severe chronic kidney disease (CKD) with a potential to progress to end-stage renal disease (ESRD). Furthermore cardiovascular (CV) diseases have been found to be related to diabetic nephropathy. CV events have been found to increase by 19–40% as the glomerular filtration rate (GFR) declines from \geq 90 mL/min/1.73 m2 to <45 mL/min/1.73 m2.⁵

Type 2 diabetes mellitus requires life-long management and the development of CKD complicates the scenario further by adding to the already elevated risk of morbidity and mortality with a significant impact on the health care infrastructure.⁶ Besides, CKD introduces many constraints in the management of diabetes.

Declining GFR limits OAD options available for achieving optimal Glycemic control resulting in higher tendency to initiate Insulin to overcome this issue. Therefore, it is important to know the level of renal impairment and current prevalence of CKD in T2DM patients. In our country, currently there is no nationwide data or registry available, looking at the burden of renal impairment in patients with T2DM with various durations of disease. This study, therefore, aims at collecting useful information in a large multi-centric setting, estimating the prevalence of CKD in such patients.

II. Materials And Methods

This observational, multi-center, cross-sectional study was conducted in the department of General Medicine, Kamineni Academy of Medical Sciences and Research Centre from January 2017 to December 2018.

Inclusion Criteria:

T2DM patients of either gender aged 30 years or above.

Exclusion criteria:

Patients with diagnosis of T1DM, acute kidney injury, symptomatic urinary tract infection, history of hematuria, known renal transplant, on maintenance dialysis, participation in any interventional study within past 3 months and pregnant women were excluded from the study. The study is aiming to enroll a total of 1000 T2DM patients, and the data from a planned interim analysis of 800 patients is presented in this paper.

This is a cross-sectional, epidemiological study, and the routine treatment as administered by the treating physician was continued without any study specific medication being administered. Patient data pertaining to demographic characteristics, disease characteristics, medical history, current medication, physical examination, and vital parameters was recorded. Data regarding diabetes complications both micro- and macro-vascular were captured as a part of history taking independent of glucose control in those patients. Blood/plasma and urine samples were collected for assessing hemoglobin A1c levels, presence of microalbuminuria, serum creatinine, urine creatinine, and routine urine analysis.

The study is being performed in accordance with Ethical principles that are consistent with the declaration of Helsinki, international conference on harmonization of technical requirements for registration of pharmaceuticals for human use - good clinical practices and guidelines issued by Indian regulatory authorities for noninterventional studies.

The primary objective of the START India study was to estimate the proportion of T2DM patients with CKD (GFR <60 ml/min/1.73 m² or albumin creatinine ratio [ACR] \geq 30 mg/g or \geq 3 mg/mmol or both) as defined by Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines. ^[12] ACR was calculated from urine creatinine and albumin, while GFR was estimated by using modification of diet in renal disease equation: eGFR (mL/min/1.73 m²) =175 × (Serum creatinine [µmol/L])^{-1.154} × age (years)^{-0.203} × 0.742 (if female) Statistical analysis was performed using SAS version 9.2 (SAS Institute, Cary, NC, USA). This paper summarizes findings of an observational study and presents primary endpoint data from the interim analysis.

III. Results

As planned we recruited 800 patients meeting the inclusion criteria from OP and IP of Kamineni Academy of Medical Sciences and Research Centre. Mean age of the study population was 54.2 years. The other demographic details are presented in Table 1. Mean duration of T2DM was 12 months. Summary of the incidence and history of diabetes-induced complications is presented in Table 2. Almost 40% of the study population was reported dyslipidemia and hypertension each, whereas the low percentage of patients had microvascular and macrovascular complications. This analysis revealed that 360 (45%) of the T2DM patients had CKD (Urinary ACR [UACR] \geq 30 mg/g and/or estimated GFR (eGFR)<60 mL/min/1.73 m2). Renal dysfunction was found as per eGFR criteria (<60 mL/min/1.73 m2) and UACR criteria (\geq 30 mg/g) in 22% and 33% of study population respectively.

S.No	Parameter	Value
1	Age in years (Mean±SD)	54.2±10.26
2	Gender (%) Female Male	360 (45) 440 (55)
3	Weight in kg (Mean±SD)	72.4±10.35
4	BMI in kg/m2 (Mean±SD)	27.2±4.21
5	BMI Group (n%) (kg/m2) Under weight <18.50 Normal: 18.50-24.99	19(2.375) 264(33)

	Over weight: 25.00-29.99 Obese: ≥30.00	356(44.5) 161(20.125)	
6	Blood pressure (mm Hg) Systolic (mm Hg) Diastolic (mm Hg)	132.5±15.27 80.25±10.34	

Table 1: Demographic characteristics (N=800)

S.No	Condition	N (%)	Mean ±SD
1	T2DM	800 (100)	103.2±86.4
2	Dyslipidemia	326(40)	
3	Hypertension	315(39.37)	
4	Microvascular complications	43(5.375)	
5	Retinopathy	21(2.625)	32.6±32.84
6	Neuropathy	34(4.25)	30.0±32.9
7	Other	12(1.5)	35.2±52.7
8	Macrovascular complications	23(2.875)	
9	Known CAD	22(2.75)	45.3±40.03
10	Stroke	2(0.25)	36.6±38.67
11	Peripheral arterial disease	1(0.125)	115.0
12	Other	1(0.125)	47.0±16.23

 Table 2: Medical history of the patients

S.No	Parameter	N (%)
1	Type 2 DM patients having CKD as per (eGFR/UACR)	360(45)
2	Renal dysfunction as per eGFR<60	176(22)
3	Renal dysfunction as per UACR≥30	264(33)

 Table 3: Renal dysfunction analysis



Figure 1: Renal dysfunction analysis

IV. Discussion

Chronic kidney disease remains an important health issue worldwide and in India. CKD requires close patient monitoring and attention as it puts major restrictions on the patient's quality of life. It places a major strain on the nation's economy and health care infrastructure. It is attributable to a number of etiologies including kidney infections, glomerulonephritis, exposure to nephrotoxins including certain drugs, and the existence of one of several risk factors in a patient including hypertension. The leading cause of CKD however, is diabetes.

In diabetic patients, in the absence of early diagnosis and appropriate management of CKD, kidney function can rapidly deteriorate to reach ESRD, when routine dialysis and eventually renal transplant could be the only treatment options. Fortunately, some of the adverse outcomes of CKD can be prevented or delayed by early intervention, including optimal glycemic control.

Our study found that over 40% of study population suffers from CKD as defined by KDOQI guidelines. While there is no nationwide data available from India, our study results seem to be similar to the CKD rates reported from other countries. A report published in 2010 by the National Health and Nutrition Examination Survey for noninstitutionalized US population indicates that CKD prevalence was 32.9% in those with diagnosed diabetes. In this survey, an eGFR of 15-59 ml/min/1.73 m² or an ACR \geq 30 mg/g at a single measurement was taken as evidence of the existence of CKD. Similarly a national diabetes audit in the UK (2011-2012), covering a total of 2.5 million diabetics found that 42.9% suffer from early CKD defined as microalbuminuria and GFR between 60 and 90 ml/min/1.73 m². Moreover, recently a large, multicentric international study, SAVOR-TIMI 53 reported that the proportion of patients with eGFR below 50 mL/min/1.73 m² is around 22% only which is in line with the SAVOR data.

One of the limitations of our study is that a single laboratory assessment was done to define the presence of CKD whereas the recommendation from international bodies is to rely on data from two visits 3 months apart. Despite this limitation, our study provides meaningful insights into the level of renal dysfunction in the studied diabetes population. In India, eGFR is frequently used as a parameter to evaluate renal function. Our study results of approximately 80% patients having a reasonably good renal function with eGFR above >60 mL/min/1.73 m² appears reassuring.

V. Conclusion

CKD is highly prevalent among patients with T2DM in India. Several risk factors for CKD are well elucidated and amenable to interventions. Our data suggest substantial unmet challenges of CKD risk factors among T2DM population. Therefore, routine screening for renal impairment and enhanced programme for global risk factors reduction is important to stem the tide of CKD in T2DM.

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