A CROSS-SECTIONAL OBSERVATIONAL STUDY TO EVALUATE THE INCIDENCE OF CHRONIC KIDNEY DISEASE IN PATIENTS WITH TYPE II TYPE DIABETES MELLITUS

Dr Atif Afzal, Dr Ansub Mateen, Dr Ali Salman
Services Institute of Medical Sciences Lahore/ Services Hospital Lahore

Abstract:
Aim: The main purpose of this study is to estimate the frequency of chronic kidney disease (CKD) in patients with type 2 diabetes (DM2).

Material and method: In this cross-sectional, observational, epidemiological, multicenter study, patients with both sexes of T2DM aged 30 years and older were registered. This study was held at Services Hospital Lahore, presents data from a planned interim analysis of 1,500 patients. The main objective of the study was CKD (glomerular filtration rate [GFR] <60 ml / min / 1.73 m2 or creatinine albumin index [ACR] ≥30 mg / g or ≥3 mg / mmol or both) in patients with T2DM. Routine treatment used by continued without any specific research intervention. Patient data on demographic characteristics, medical history, current drug treatment and physical examination were recorded. Blood / plasma and urine samples were collected to assess hemoglobin A1c, microalbuminuria, serum creatinine, urine creatinine and routine urinalysis. ACR was calculated from creatinine and urine albumin, while GFR was calculated using diet modification in the renal disease equation.

Results: 1500 patients were included in the study. There were 840 (56.05%) men in the studied population. Mean age, body mass index and systolic blood pressure were 55.1 years, 27.4 kg / m2 and 134.5 mmHg, respectively. The average duration of diabetes was 102.2 months. A history of comorbidities such as dyslipidemia, hypertension, microvascular and macrovascular complications occurred in 657 (43.8%), 655 (43.7%), 268 (17.9%) and 104 (6.93%), respectively. This mid-term analysis showed that approximately 46% of patients with DM2 had CKD (urinary albumin creatinine ratio (UACR) ≥30 mg / g and / or GFR [eGFR] <60 ml / min / 1.73 m2). According to EGFR criteria (<60 ml / min / 1.73 m2), renal impairment was reported in approximately 23%, according to UACR criteria (≥30 mg / g) in approximately 35% of patients. patients

Conclusion: Indirect analysis results show that over 40% of patients with DM2 have CKD. Despite such a large number of patients with DM2 with CKD, eGFR analysis shows that almost 80% of patients with DM2 still have fairly good kidney function (GFR above 60 ml / min), which guarantees less limitations in the oral selection of antidiabetic drugs.

Key words: creatinine albumin ratio, chronic kidney disease, diabetes, glomerular filtration rate, renal dysfunction.

Corresponding author:
Dr. Atif Afzal,
Services Institute of Medical Sciences Lahore/ Services Hospital Lahore

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INTRODUCTION:

Diabetes is a major cause of anxiety due to the increasing prevalence worldwide. Transport growth is highest in Asian and African countries. According to estimates, in 2013, 382 million people worldwide, between the ages of 20 and 79, lived with diabetes, 46% of whom were not diagnosed. This number is expected to increase to 592 million by 2035. According to the International Atlas of the International Federation of Diabetes 2013, Pakistan admits 65.1 million diabetic patients. Asian develop diabetes and are currently estimated to be about 10 years lower than their Western counterparts. The increase in prevalence of type 2 diabetes (DM2) is associated with an increase in the frequency of complications associated with microvascular and macrovascular complications, including kidney disease. Diabetes is found to be the leading cause of renal failure in approximately 45% of dialysis patients. Diabetic nephropathy is one of the most common microvascular complications of DM2. US population data suggest that approximately 15–23% of patients with diabetes are moderate to severe chronic kidney disease (CKD), with the possibility of transition to end stage renal disease (ERT). Cardiovascular disease (CV) has also been found to be associated with diabetic nephropathy. CV events increased by 19-40% when the glomerular filtration rate (GFR) decreased from ≥ 90 ml / min / 1.73 m2 to <45 ml / min / 1.73 m2. Type 2 diabetes requires lifelong treatment, and the development of CKD further increases the already high risk of morbidity and mortality, which has a significant impact on health infrastructure, making this scenario even more complicated. In addition, CKD imposes many restrictions on the treatment of diabetes. Reducing GFR limits the available OAD options to achieve optimal glycemic control, which usually initiates insulin to overcome this problem. It is therefore important to know the level of renal failure and the current prevalence of CKD in patients with T2DM. Currently, there are no data or records in our country that would analyze the burden of renal failure in patients with T2DM at various national levels. Therefore, this study aims to collect useful information in a broad, multi-center environment by predicting the incidence of CKD in such patients.

MATERIAL AND METHODS:

Patients with DM2 aged 30 years and older than both sexes were included in this observational, multi-center cross-sectional study. Patients diagnosed with T1DM, acute kidney damage, symptomatic urinary tract infection, history of hematuria, known renal transplantation, caring dialysis, participation in any intervention during the last 3 months and pregnant women were excluded. The aim of the study is to register a total of 3,000 patients with T2DM, and this document presents data from a planned periodic analysis of 1,500 patients. This is a cross-sectional epidemiological study, and the doctor continued routine treatment without special treatment. Patient data on demographic characteristics, disease characteristics, medical history, current medications, physical examination and vital signs were recorded. Data on both microvascular and macrovascular diabetes complications were included as part of the article, regardless of glycemic control in these patients. Blood / plasma and urine samples were collected to assess hemoglobin A1c, microalbuminuria, serum creatinine, urine creatinine and routine urine analysis.

The study is conducted in accordance with ethical principles. The main purpose of the study is to estimate the ratio of T2DM patients with CKD (GFR <60 ml / min / 1.73 m2 or creatinine to albumin ratio [ACR] ≥ 30 mg / g or ≥ 3 mg / mmol or both) Kidney disease. When calculating ACR from creatinine and albumin in the urine, the diet was estimated in the equation of renal disease with GFR, changing: eGFR (ml / min / 1.73 m2) = 175 × (serum creatinine [µmol / L]) - 1.154 × age (years). 200.203 × 0.742 (women If) Statistical analysis was performed using SAS version 22.0 (SAS Institute, Cary, NC, USA). This document summarizes the results of the observational study and presents data on the primary endpoint from interim analysis.

RESULTS:

According to the plan, we recruited 1,500 patients across the country who met the criteria for including 18 centers. The average age of the studied population was 55.1. Other demographic details are shown in Table 1.

Table 1: Demographic characteristics of study patients (*n*=1500)

Parameter	Value
Age in years (mean±SD)	55.1±11.37
Gender (%)	
Female	660 (44.0)
Male	840 (56.0)
Weight in kg (mean±SD)	71.3±13.52
BMI in kg/m² (mean±SD)	27.4±4.82
BMI group (*n* %) (kg/m²)	
Underweight: <18.50	20 (1.33)
Normal: 18.50-24.99	473 (31.5)
Overweight: 25.00-29.99	618 (41.2)
Obese: ≥30.00	389 (25.9)
Blood pressure (mmHg)	
Systolic (mean±SD)	134.5± 16.60
Diastolic (mean±SD)	79.8±10.49

SD: Standard deviation, BMI: Body mass index

The average duration of DM2 was 102 months. A summary of the occurrence and history of complications due to diabetes is presented in Table 2.

Table 2: Medical history of study patients (*n*=1500)

Condition	*n* %	Average duration in months mean±SD
T2DM	1500 (100)	102.2±87.78
Dyslipidemia	657 (43.8)	
Hypertension	655 (43.7)	
Microvasuclar complications	268 (17.9)	
Retinopathy	50 (2.81)	33.3±33.92
Neuropathy	167 (9.38)	30.0±33.04
Nephropathy	58 (3.26)	36.1±57.55
Other	25 (1.40)	34.7±41.14
Macrovascular complications	104 (6.93)	
Known CAD	90 (5.05)	46.4±40.02
Stroke	13 (0.73)	37.8±40.84
Peripheral arterial disease	1 (0.06)	120.0
Other	2 (0.11)	48.0± 16.97

CAD: Coronary artery disease, SD: Standard deviation, T2DM: Type 2 diabetes mellitus

Almost 44% of the studied population reported dyslipidemia and hypertension, while a low percentage of patients had microvascular and macrovascular complications. This analysis showed that 697 (46.47%) patients with DM2 had CKD (urinary ACR [UACR] ≥30 mg / g and / or estimated GFR (eGFR) <60 ml / min / 1.73 m2). Renal impairment was found in accordance with the criteria eGFR (<60 ml / min / 1.73 m2) and UACR (≥30 mg / g) in 22.60% and 34.5% of the study population, respectively. More details of the analysis are presented in Table 3.

Table 3: Renal dysfunction analysis of study patients (*n*=1500)

	(*n*=1500)
T2DM patients having CKD as per (eGFR/UACR)	697 (46.47)
Renal dysfunction as per eGFR <60	339 (22.60)
Renal dysfunction as per UACR ≥30	518 (34.53)

CKD: Chronic kidney disease, eGFR: Estimated glomerular filtration rate, UACR: Urine albumin: Creatinine ratio, T2DM: Type 2 diabetes mellitus

DISCUSSION:

Chronic kidney disease remains a major health problem worldwide and in India. CKD requires close monitoring and patient care because it imposes significant restrictions on the patient's quality of life. It puts a lot of pressure on the national economy and health infrastructure[10-11]. This can be attributed to many etiologies, such as kidney infections, glomerulonephritis, exposure to nephrotoxins containing certain medications, and the presence of one of several risk factors, including patient hypertension. However, diabetes is the main cause of CKD. In patients with diabetes, when early diagnosis and CKD are not adequately treated, routine dialysis and ultimately kidney transplantation may be the only treatment option, and renal function may rapidly deteriorate to achieve ERT[12-13]. Fortunately, early interventions can prevent or delay some of the negative consequences of CKD, including optimal glycemic control.

Our study showed that more than 40% of the study population suffered from CKD as described in the KDOQI guidelines. Although there is no national level data in India, the results of our study appear similar to the CKDs reported in other countries. Report published in 2010 by the National Health and Nutrition Survey for the non-institutional population of EE. Laws show that the incidence of CKD is 32.9% in people diagnosed with diabetes. In this study, an eGFR of 15-59 ml / min / 1.73 m2 in a single measurement or ≥30 mg / g ACR in a single measurement was taken as evidence for CKD. Similarly, in the United Kingdom (2011–12), national diabetes surveillance covering a total of 2.5 million people suffered from 42.9% suffering from early CKD, defined as 60–90 ml / min microalbuminuria and GFR. Found / 1.73 m2. In addition, the international multicenter study SAVORTIMI 53 recently found that, despite the average duration of diabetes, the percentage of patients with eGFR less than 50 ml / min / 1.73 m2 was approximately 16%. 10 years. Our study showed that the percentage of patients with eGFR below 60 ml / min / 1.73 m2 is approximately 22% according to SAVOR data[14-15]. One of the limitations of our study is the assessment from one laboratory to detect the presence of CKD, and the council of international organizations relies on data from two visits every 3 months. Despite this limitation, our study provides important information about the level of renal impairment in the study population of diabetes. In Pakistan, eGFR is often used as a parameter to assess renal function. The results of our study seem to calm down about 80% of patients with fairly good renal function above> 60 ml / min / 1.73 m2 with EGFR.

CONCLUSION:

Temporary data analysis provides valuable information on the level of kidney dysfunction in the DM2 population in this country from a national study. Full study results will provide detailed information on CKD formation in T2DM patients in Pakistan.

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