
Non-Interventional Study (NIS) Report

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**An Observational, Cross sectional STudy to Assess the Prevalence
of ChRonic Kidney Disease in Type 2 Diabetes Patients in **India**
(START-India)**

Study dates: 26-Sep-2014 to 26-May-2015

First Subject In: 26-Sep-2014

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NIS REPORT SYNOPSIS

An Observational, Cross sectional Study to Assess the Prevalence of Chronic Kidney Disease in Type 2 Diabetes Patients in India.

Name of Sponsor /Company: AstraZeneca Pharma India Ltd.

Investigators and sites: The study was conducted at 30 sites in India. Each site had one study Investigator.

Study Period: 26-Sep-2014 to 26-May-2015

Phase of Development: Not applicable.

Rationale: Patients with Type 2 Diabetes Mellitus (T2DM) invariably develop some level of renal dysfunction during the course of disease which may lead to the development of Chronic Kidney disease (CKD). In addition to T2DM, the CKD itself is associated with increase in morbidity and mortality. But the data regarding the prevalence of CKD in India is limited. It is with this objective in mind, the current study was planned to collect information about prevalence of chronic kidney dysfunction along with other parameters in T2DM patients.

Objectives:

Primary: To determine the prevalence of Chronic Kidney Disease in patients with T2DM.

Secondary:

- a) To estimate the proportion of T2DM patients in various Categories of Glomerular Filtration Rate (GFR).
- b) To estimate the proportion of Chronic Kidney Disease in T2DM patients with different duration of diabetes since diagnosis.
- c) To estimate the Glycated Hemoglobin (HbA1c) goal achievement in patients with and without CKD.
- d) To observe anti-diabetic treatment in study population and their association with renal failure.
- e) To observe treatment pattern of anti-hypertensive and anti-dyslipidimic medications in study population and their association with renal failure.

Study design: This was an observational, multicenter, cross-sectional study conducted at 30 sites in India for estimating the prevalence of CKD in T2DM patients.

Number of subjects (planned and analysed): Planned - 3000
Analysed - 3000

Inclusion criteria:

1. Known cases of T2DM.
2. Male and female patients of age 18 years and above.
3. Must provide written Informed Consent.

Exclusion criteria:

1. Patients with known type-1 diabetes
2. Patients with any form of acute kidney injury based on investigator's discretion,
3. Patients on maintenance dialysis or known renal transplant patients.
4. Patients who have participated in any interventional study within past 3 months prior to entry in this study.
5. Pregnant women.
6. Patients with symptomatic Urinary Tract Infection (UTI) or with history of hematuria.

Study variable(s):

- Primary variable is the proportion of T2DM patients with CKD.
- Secondary variables: Frequency of the following among T2DM patients:-
 - a) Various stages of CKD.
 - b) CKD in patients with different duration of T2DM.
 - c) HbA1C less than 7% in T2DM patients with and without CKD.
 - d) Anti-diabetic medications and relationship of intake of anti-diabetic medications with renal failure.
 - e) Anti-hypertensive and anti-dyslipidemic medications and relationship of intake of anti-hypertensive and antidyslipidemic medications with renal failure.

Statistical methods: All the analysis was done by SAS version 9.2. Descriptive analysis was done for quantitative variables. Chi square test was done for finding association of qualitative variables. Full analysis set was used for the purpose of analysis.

Result:

The study had 53.9% male population, and the mean age, duration of diabetes, BP measurements and BMI of the study population were 53.4 years, 97.5 months, 132.4/79.5 mmHg and 27.3 kg/m² respectively. The prevalence of CKD in our study was 48.4%. Details of level of eGFR & ACR are given in **Table 1**. Proportion of patients having HbA1C of <7% was higher in patients without CKD (30%) vs. with CKD (23.4%). Surprisingly duration of disease had no significant impact on CKD occurrence.

This study results of 40% T2DM patients having CKD is an eye opener for India which is home to > 65 million people with diabetes. Despite high prevalence of CKD more than 90% patients have eGFR >45 ml/min

Table 1: Summary of Various CKD Stages in T2DM Patients

(N=3000)	
As per GFR categories in CKD, n (%)	
G1 (Normal or High)	843(28.1%)
G2 (Mildly decreased)	1433(47.8%)
G3a (Mild to moderately decreased)	453(15.1%)
G3b (moderately to severely decreased)	188(6.27%)
G4 (Severely decreased)	55(1.83%)
G5 (Kidney Failure)	22(0.73%)
Missing	6(0.20%)
As per Albuminuria categories in CKD, n (%)	
A1 (Normal to mildly increased)	1840(61.3%)
A2 (Moderately increased)	767(25.6%)
A3 (Severely increased)	215(7.17%)
Missing	178(5.93%)

CKD = Chronic Kidney Disease, T2DM = Type 2 Diabetes Mellitus

GFR values (ml/min/1.73m²): G1= >=90, G2= 60-89, G3a= 45-59, G3b= 30-44, G4= 15-29, G5= <15

Albumin to Creatinine Ratio (mg/g): A1= <30, A2= 30-300, A3= >300

Date of the Report: 30-09-2015
